

Thanks,  
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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**From:** Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 9/4/2020 4:44:15 PM  
**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)  
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(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adadfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];  
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim,

Elizabeth [ (b) (6) ] btoiman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) ] Diamond, Michael [ (b) (6) ] Rose Li [ (b) (6) ] Dana Carluccio [ (b) (6) ]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [ (b) (6) ] Dave Frankowski [ (b) (6) ] Baric, Toni C [ (b) (6) ] Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [ (b) (6) ] (b) (6)

**Subject:** ACTIV Preclinical full working group

**Location:** https://fnih.zoom. (b) (6)

**Start:** 9/23/2020 2:30:00 PM

**End:** 9/23/2020 3:30:00 PM

**Show Time As:** Tentative

**Recurrence:** Weekly  
every Wednesday from 10:00 AM to 11:00 AM

**Required Attendees:** Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6)  
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(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];  
(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];  
Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];  
Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

**Optional Attendees:** Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b) (6)

Changing time for this meeting at the request of the cochair.



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**Sent:** 4/24/2020 11:29:47 PM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [ (b) (6) Butterson, Joan [ (b) (6) Collins, Sylva (FDA/CDER) (b) (6) ]; Judy Currier [ (b) (6) .edu]; De Claro, R. Angelo (FDA/CDER) [ (b) (6) Mark Eisner [ (b) (6) Keith Gottesdiener [ (b) (6) Eric Hughes [ (b) (6) LaVange, Lisa M [ (b) (6) Elliott Levy [ (b) (6) Sandeep Menon [ (b) (6) Amanda Peppercorn [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [proschan@niaid.nih.gov]; Read, Sarah (NIH/NIAID) [E] [ (b) (6) Amanda Peppercorn [ (b) (6) Price, Dionne (FDA/CDER) [ (b) (6) Rubin, Daniel B. (FDA/CDER) [ (b) (6) Shen, Yuan Li (FDA/CDER) [ (b) (6) Farley, John (FDA/CDER) [ (b) (6) Goff, David (NIH/NHLBI) [E] [ (b) (6) Vincent, Michael [ (b) (6) Wung, Peter /US [ (b) (6)  
**CC:** Mary Biggs [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6) Wachtel, Jonathan [ (b) (6) Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [ (b) (6) Wholley, David (FNIH) [T] [ (b) (6) Melencio, Cheryl (FNIH) [T] [ (b) (6)  
**Subject:** ACTIV TX-Clinical Master Protocol Subgroup Meeting #11  
**Attachments:** ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting Agenda\_05012020.pdf; ACTIV Therapeutics-Clinical\_MP Subgroup\_1May2020 Meeting Guide.pdf  
**Location:** [https://fnih.zoom.us/j/ \(b\) \(6\)](https://fnih.zoom.us/j/(b)(6))  
**Start:** 5/1/2020 3:00:00 PM  
**End:** 5/1/2020 4:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US  
**Optional Attendees:** Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for today's meeting.  
Please let me know if you have any questions.

Thanks,  
Stacey

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**From:** Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]  
**Sent:** 5/30/2020 1:01:41 AM  
**To:** Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]  
**CC:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Elsaid, Olivia [REDACTED] (b) (6)  
**Subject:** RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30  
**Attachments:** ACTIV Therapeutics\_053020.pptx

Hi all,

Thanks, this is an excellent set, though to keep the discussions with Moncef concise, I've moved some of the slides to the Appendix. See current version. I will send this to Janet now too.

One question: when the immunomodulator slide 7 says this:

*All 3 agents have Initial Phase II data or are currently running company-sponsored Phase II trials*

What does that mean? Phase II trials for what application?

Francis

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**From:** Gonzalez, Nina <[REDACTED] (b) (6)>  
**Sent:** Friday, May 29, 2020 8:37 PM  
**To:** Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>  
**Cc:** Adam, Stacey (FNIH) [T] <[REDACTED] (b) (6)> Wholley, David (FNIH) [T] <[REDACTED] (b) (6)> Freire, Maria (FNIH) [T] <[REDACTED] (b) (6)> Parker, Ashley (NIH/OD) [E] <[REDACTED] (b) (6)> Elsaid, Olivia <[REDACTED] (b) (6)>  
**Subject:** RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi Francis,

See attached the latest version of the slides for the meeting tomorrow.

We'll be on standby for any edits you may have.

Thank you,

Nina

**Nina Gonzalez**  
Deloitte Consulting LLP

APAR0000001310-2517061

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**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Sent:** Friday, May 29, 2020 8:32 PM  
**To:** Wholley, David (FNIH) [T] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] (b) (6); Freire, Maria (FNIH) [T] (b) (6) Gonzalez, Nina  
(b) (6); Parker, Ashley (NIH/OD) [E] (b) (6)  
**Subject:** [EXT] RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hoping these are coming to me soon, as I may want to do some editing -- and then I wanted to run them past Janet tonight.

FC

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**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Friday, May 29, 2020 7:41 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gonzalez, Nina  
(b) (6); Parker, Ashley (NIH/OD) [E] (b) (6) Freire, Maria (FNIH) [T]  
(b) (6)  
**Subject:** RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Have seen and offered a few changes to the complete slide deck. They should be coming back to you as soon as Deloitte makes the changes.

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**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Friday, May 29, 2020 5:59 PM  
**To:** Wholley, David (FNIH) [T] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] (b) (6) Freire, Maria (FNIH) [T] (b) (6) >; Gonzalez, Nina  
(b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6)  
**Subject:** RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note -- has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis



**From:** Wholley, David (FNIH) [T] (b) (6) >  
**Sent:** Friday, May 29, 2020 1:59 PM  
**To:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Cc:** Adam, Stacey (FNIH) [T] < (b) (6) >; Freire, Maria (FNIH) [T] < (b) (6) >; Gonzalez, Nina (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) >  
**Subject:** Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
  - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
  - ACTIV hiVIG (sponsored by NIAID) – in progress
  - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
  - ACTIV-2\* – Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
  - ACTIV-3\* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
  - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) – (Phase II/III) – projected launch late June
  - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August (*if needed; i.e. if agents are not incorporated into mAb protocols*)
    - \* current priority

[for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)  
[Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
  - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
  - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
  - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
  - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)

- Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
- Protocol is 80% complete
  - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
    - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
  - All three companies have written their sections of the protocols, which are being merged into the master design
- Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- “ACTIV-4” Protocol for anticoagulants
  - Need bullets from NHLBI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley  
 Senior Vice-President, Research Partnerships  
 Foundation for the National Institutes of Health

(b) (6)

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**Sent:** 5/28/2020 3:45:50 PM

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**CC:** Demarcus [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tojtaskh]; Wachtel, Jonathan [ (b) (6) Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [ (b) (6) Eron, Joseph J Jr [ (b) (6) Smith, David [ (b) (6) Paul Klekotka [ (b) (6) Ajay Nirula [ (b) (6) Lucas Smalldon [ (b) (6) Rose Li Central Account [ (b) (6) Dana Carluccio [ (b) (6) Chen, Helen Q. [ (b) (6)

**Subject:** RE: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update

Of interest re interpreting virology - <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa638/5842165>

-----Original Appointment-----

**From:** Adam, Stacey (FNIH) [T] < (b) (6) >

APAR0000005271-2517062

**Sent:** Saturday, May 23, 2020 1:02 PM

**To:** Adam, Stacey (FNIH) [T]; Judy Currier; Eric Hughes; LaVange, Lisa M; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; (b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6) Kim, Peter (NIH/NIAID) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner, Bugin, Kevin (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)

**Cc:** Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr, Smith, David; Paul Klekotka; Ajay Nirula; Lucas Smalldon; Rose Li Central Account; Dana Carluccio; Chen, Helen Q.

**Subject:** ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update

**When:** Wednesday, May 27, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

**Where:** <https://fnih.zoom.us>, (b) (6)

Dear ACTIV-2 Writing Team and ACTIV mAb Steering Committee,

We are looking forward to this joint meeting tomorrow in which the ACTIV-2 team will share their progress on the mAb outpatient master protocol with the Steering Committee. The team will review the current thinking within the protocol. Then they would like to solicit feedback from the Steering Committee about a few remaining questions that could still alter the protocol structure.

Please find attached the materials for tomorrow:

1. Meeting agenda
2. Current ACTIV-2 master protocol
3. Slides summarizing the current protocol

Please note that the stats team is still working to insert the final design of the Bayesian framework that will be used for agents beyond the first drug(s) into the trial for progression from Phase 2 to 3 within the study. This framework will not apply to the early entrants since prior learnings will be needed to inform the Bayesian model.

In addition, the team is waiting on some critical feedback from the FDA about how to address company feedback for a Phase 1(ish) safety/dose "run-in" study protocol that could be paired with the master protocol and potentially be overseen by ACTIV.

Thanks,  
Stacey

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Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (david. (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Krchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]; (b) (6) (b) (6) (b) (6) (b) (6) dona.d.banerji (b) (6) lorraine.bandelli@novartis.com; diane.bonagu (b) (6) (b) (6) Feltquate, David; Larry Tsai

**Optional Attendees:**

Chen, Helen Q., Sorosa, Alex David; Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Menetski, Joseph (FNIH) [T]; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; (b) (6) Molica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex; Lumsden, Joanne (NIH/NCATS) [C]; Lerner, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; LEVINE, MICHAEL; Armstrong, Linda

**From:** Santos, Michael (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]

**Sent:** 4/22/2020 6:42:18 PM

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[ (b) (6) Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative  
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Bethany Stokes  
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**Subject:** ACTIV Vaccines Working Group meeting

**Location:** Webex: <https://nih.webex.com/nih> (b) (6)

**Start:** 5/5/2020 4:00:00 PM

**End:** 5/5/2020 5:00:00 PM

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**Required Attendees:** (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann;  
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Emi (b) (6) emmanuel. (b) (6) Haynes, Barton; (b) (6) (b) (6)  
(b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy  
(CDC/DDID/NCIRD/OD); Offit, Paul; (b) (6) Seals, Jonathan (OS/ASPR/BARDA);  
(b) (6) Tal Zaks  
**Optional Attendees:** Tolman, Brett; (b) (6) Hopps, Markay; Kozlowsk, Mary (NIH/NCI) [C]; Johnson, Maureen  
(NIH/NCI) [E]; (b) (6) (b) (6) (b) (6)  
(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,  
Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Whol ey, David (FNIH) [T];  
Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James Stephanie (FNIH) [T]; Colvis,  
Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID)  
[E]; Young, John; Gonzalez, Nina; (b) (6) (b) (6) Wachtel,  
Jonathan; Arvin, Ann; Anderson, Margaret; Marston, Hilary (NIH/NIAID) [E]; Bethany Stokes

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(b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];

(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] (b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6) ]; Hewitt, Judith (NIH/NIAID) [E] (b) (6) ; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];

(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];

(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas (b) (6)

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melenc o, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Hughes, Enc [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [ (b) (6) Kim, Elizabeth [ (b) (6) Tolman, Brett [ (b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) Rose Li [ (b) (6) Dana Carluccio [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [ (b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [ (b) (6) Dave Frankowski [ (b) (6) Baric, Toni C [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Diamond, Michael [ (b) (6)

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**Start:** 5/26/2020 6:00:00 PM  
**End:** 5/26/2020 7:00:00 PM

**Recurrence:** (none)

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 (b) (6) (b) (6) (b) (6) (b) (6)  
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 (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] (b) (6) Colvis, Christine  
 (NIH/NCATS) [E] (b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) ; Deming, Damon  
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 [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6)  
 Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc  
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Isis. (b) (6)  
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 CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher  
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 [ (b) (6) Kim, Elizabeth (b) (6) btolman [ (b) (6) Wachtel,  
 Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) Diamond, Michael  
 [ (b) (6) Rose Li [ (b) (6) Dana Carluccio  
 [dana.carluccio (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses];  
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [ (b) (6) Dave Frankowski [ (b) (6) antoinette\_baric [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]; Stratton, Benjamin [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [ (b) (6) Mason, Stephen [ (b) (6) (b) (6) Connolly, Sarah [ (b) (6) (b) (6) .com; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent L oyd [ (b) (6) (b) (6) Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Desrosiers, Betsy [ (b) (6) Gonzalez, Nina [ (b) (6)

**Start:** 4/14/2021 2:00:00 PM  
**End:** 4/14/2021 3:00:00 PM

**Recurrence:** (none)

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**From:** Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
**Sent:** 4/28/2020 3:02:20 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**CC:** Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]  
**Subject:** Agent Prioritization Committee and Process

Hi Francis,

As requested on this morning's call here is the membership of the Agent Prioritization Sub Group of the Therapeutics-Clinical WG and a summary of the approach they are taking to prioritize agents for testing in ACTIV. As I mentioned and is indicated below, relevant MOA is a primary criterion for initial sorting of candidates. Please let me know if you have additional questions regarding this. David

#### **Main Review Committee**

- Eric Hughes – Novartis
- Sarah Read - NIAID
- Timothy Buchman - BARDA
- Ruxandra Draghia Akli – J&J
- Keith Gottesdiener – COVID-19 R&D Leaders Consortium
- Elliott Levy - Amgen
- John Mellors – U. Pittsburgh
- Namish Patel - Sanofi
- Mike Vincent – Pfizer (member of Clinical Trials WG)
- Peter Wung – Sanofi and JHU
- John Young - Roche
- Christine Colvis - NCATS
- Libby Higgs - NIAID

#### **Tie-breaker Reviewer (if needed)**

- Walter Koroshetz - NINDS

#### **Strategic Guidance (Non-Voting)**

- Peter Stein – FDA (CDER)
- Mike Poole – BMGF (Therapeutics Accelerator Lead)

#### **Current Process**

The current agent prioritization process is a multistage process.

1. Step 1: The FNIH team and the co-chairs divided the original list of agents pulled from publicly accessible data (~400 compounds) "Wave Groups" via their stage in development, i.e. FDA-approved/IND-enabled, Clinically ready, Preclinical.
2. Step 2: The Main Review Committee is currently triaging the list of agents that were FDA-approved/IND-enabled or strongly clinical ready and that were grouped by Mechanisms of Actions (MOA) (~170 agents) to

quickly evaluate relevant MOAs, perceived best in class for most relevant MOAs, and thereby whittle down agents for use in the first master protocol planned. The “repurposed” master protocol which is imagined to be a larger Phase III trial of at least 3 agents ready for this stage. Each compound is being assessed for triage by two reviewers.

3. Step 3: The Main Review Committee will meet to adjudicate or have the tie-breaker reviewer decided on any agents where the first two reviewers disagree on the triage status.
4. Step 4: Any agents that make it through the triage process (likely ~30-40 agents) will be scored by each of the Main Review Committee members individually (per Larry Tabak’s request) via the Agent Prioritization Scoring Criteria that was selected by the group, and based on data that is available in the public domain. This will happen between Tuesday night to Thursday afternoon this week of the process continues on pace.

#### Agent Prioritization Criteria for Wave 1

Rationale for MOA to be relevant to COVID-19	SARS-CoV2 Trials	Preclinical data (SARS-CoV2)	PK/PD	Safety	Drug-Drug Interactions	Availability/Scalability
Strong (2)	Data from one or more small RCTs (3)	In vivo data in appropriate animal model (3)	Sufficient plasma and tissue(lung) levels (3)	No concerns (3)	None (1)	Already sufficient drug in stock to begin large trials (3)
Weak (1)	Data from one or more uncontrolled trials (2)	In vitro viral inhibition data in multiple relevant cell lines (2)	Sufficient plasma levels (2)	Minor concerns (1-2)	Clinically Significant DDIs (0)	Drug in stock with ability to manufacture enough for trial in short timeframe (2)
None (No Go)	Case series, anecdotal data (1)	In vitro suggestive mechanism data (1)	Insufficient data to judge (0)	Insufficient data to judge 0)		Manufacturing capabilities available, but not ramped up (1)
	None (0)	None (0)	Insufficient levels (No Go)	Major concern (No Go)		Not scalable at this time (No Go)

5. Step 5: The FNIH/Deloitte Team will compile and average the scores for this agents and create a rank priority list.
6. Step 6: The Agent Prioritization will then discuss the list and see which of the top compounds could easily be paired together for the “repurposed” master protocol and which may require other avenues for testing, such as the “de novo” master protocol.
7. Step 7: For the agents that are chosen, the FNIH/Deloitte team will outreach to the companies, if they are not already part of ACTIV, to ensure appropriate drug supply. If there is enough agent to be tested or it can be manufactured in the next month, the agent will proceed for the “repurposed” master protocol. If not, the agent will be considered in for future testing based on the supply.
8. All agents not chosen for the first round that are not disqualified for safety will be re-evaluated for the next set of agents to be tested.

**From:** Eakin, Ann (NIH/NIAID) [E] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=7DAFBA298C194F9D9BC13C54FE0CF29A-EAKINAE]  
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**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [ (b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [ (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [ (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [ (b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [ (b) (6) Keith Gottesdiener [ (b) (6) Elliott Levy [ (b) (6) Wung, Peter /US [ (b) (6) Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [ (b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Alvarez, Rosa Maria [ (b) (6) Rose Li [ (b) (6) Mark Krystal [ (b) (6) Prabhavathi Fernandes [ (b) (6) Diamond, Michael [ (b) (6) Sanderson, Philip (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee2d44e63f2645708a3beb2ea1b280a1-sandersonpe]; Tressler, Randal (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c1978dd53134e13ac736758e8b8756f-tressler]; [ (b) (6) Dana Carluccio [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Sumit Chanda [ (b) (6) Rich Colunno [ (b) (6) ]; Fisher, Robert (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=706cb01f58ef4042aecc4de5ab72ec1-Robert.Fish]  
**CC:** Chen, Helen Q. [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [ (b) (6) Salathin, Carla [ (b) (6) [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**Subject:** Re: Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting

I can make 3:30 but not 3.

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**From:** Adam, Stacey (FNIH) [T] < (b) (6) >  
**Sent:** Wednesday, July 1, 2020 8:59:48 PM  
**To:** Eric Hughes < (b) (6) >; Read, Sarah (NIH/NIAID) [E] < (b) (6) >; Ruxandra Draghia-Akli < (b) (6) >; Mellors, John W < (b) (6) >; Naimish Patel < (b) (6) >; Colvis, Christine (NIH/NCATS) [E] < (b) (6) >; Young, John < (b) (6) >; Stein, Peter (FDA/CDER) < (b) (6) >; Poole, Mike < (b) (6) >; Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) >; Vincent, Michael < (b) (6) >; Keith Gottesdiener < (b) (6) >; Elliott Levy < (b) (6) >; Wung, Peter /US < (b) (6) >; Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) >; Higgs, Elizabeth



(NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Carlos O Garner <(b) (6)> Goff, David (NIH/NHLBI) [E]  
 <(b) (6)> Alvarez, Rosa Maria <(b) (6)> dale.j. <(b) (6)>  
 <(b) (6)> Rose Li <(b) (6)> Mark Krystal <(b) (6)>  
 Prabhavathi Fernandes <(b) (6)> Diamond, Michael <(b) (6)> Sanderson,  
 Philip (NIH/NCATS) [E] <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Tressler,  
 Randall (NIH/NIAID) [E] <(b) (6)> <(b) (6)> <(b) (6)>  
 Eakin, Ann (NIH/NIAID) [E] <(b) (6)> Young, John <(b) (6)> Mellors, John W  
 <(b) (6)> Higgs, Elizabeth (NIH/NIAID) [E] <(b) (6)> Dana Carluccio  
 <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Sumit Chanda  
 <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)> <(b) (6)>  
 <(b) (6)> Draghia Akli, Ruxandra [JRDUS] <(b) (6)> Hughes, Eric  
 <(b) (6)> <(b) (6)> <(b) (6)> Rich Colonno  
 <(b) (6)> Fisher, Robert (FDA/OC) <(b) (6)>  
 Cc: Chen, Helen Q. <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Alvarez, Rosa Maria  
 <(b) (6)> Salathin, Carla <(b) (6)> <(b) (6)> <(b) (6)>  
 <(b) (6)> <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> <(b) (6)>  
**Subject:** RE: Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting

Dear ACTIV TX-Clinical Agent Prioritization Subgroup and Antiviral Subteam,

While I could not get quorum for the 12-1pm slot for our discussion tomorrow, many of you said you could be available after 3pm. Therefore, could you all let me know if 3-4pm ET tomorrow would work for you to meet?

Thanks,  
 Stacey

**Stacey J. Adam, PhD**

Director, Cancer

Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

**From:** Adam, Stacey (FNIH) [T]

**Sent:** Tuesday, June 30, 2020 10:55 PM

**To:** Eric Hughes <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Ruxandra Draghia-Akli <(b) (6)> John Mellors <(b) (6)> Naimish Patel <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Young, John <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Poole, Mike <(b) (6)> Buchman, Tim (OS/ASPR/BARDA) (CTR) <(b) (6)> Vincent, Michael <(b) (6)> Keith Gottesdiener <(b) (6)> Elliott Levy <(b) (6)> Wung, Peter /US <(b) (6)> Koroshetz, Walter (NIH/NINDS) [E] <(b) (6)> Higgs, Elizabeth (NIH/NIAID) [E] <(b) (6)> Carlos O Garner <(b) (6)> Goff, David (NIH/NHLBI) [E] <(b) (6)>  
 Cc: Chen, Helen Q. <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Alvarez, Rosa Maria <(b) (6)> Salathin, Carla <(b) (6)> GM <(b) (6)> J <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Subject:** Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

We would like to have a meeting on Thursday with this team and the Antiviral review subteam to discuss and finalize the Antiviral Subgroup's selections from this latest Wave of prioritization.

Please let me know if you would be able to attend this meeting from 12-1pm ET.

Thanks,  
Stacey

**Stacey J. Adam, PhD**

Director, Cancer

Research Partnerships

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 6/26/2020 1:23:02 AM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Sandeep Menon [ (b) (6) Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William Erh]; Roger Paredes [ (b) (6) Andrew Phillips [ (b) (6)  
**CC:** Demarcus [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [ (b) (6) Eron, Joseph J Jr (b) (6) Chew, Kara M.D. [ (b) (6) Daar, Eric [ (b) (6) rg]; Erhardt, William (HHS/IOS) (b) (6)

**Subject:** Canceled: ACTIV-3 Standing Protocol Team Meeting  
**Attachments:** Untitled Attachment; Canceled: ACTIV-3 Writing Team; Untitled Attachment  
**Location:** <https://fnih.zoom.us/> (b) (6) 09

**Start:** 6/29/2020 3:00:00 PM  
**End:** 6/29/2020 4:00:00 PM  
**Show Time As:** Free

**Recurrence:** Weekly  
every Monday from 11:00 AM to 12:00 PM

**Required Attendees:** Jens Lundgren; Wentworth, Deboy; (b) (6) (b) (6) Ajay Nirula - Lilly; (b) (6) Patterson, Amy (NIH/NHLBI) [E]; Andrew Phillips; (b) (6) (b) (6) Birgit Grund (b) (6) (b) (6) Lane, Cliff (NIH/NIAID) [E]; (b) (6) (b) (6) Higgs, Elizabeth (NIH/NIAID) [E]; Emil (b) (6) (b) (6) Ginny Kan; Baker, Jason; (b) (6) (b) (6) Neaton, J m; (b) (6) Judy Currier; (b) (6) (b) (6) Reineck, Lora (NIH/NHLBI) [E]; Kozak, Marina (OS/ASPR/BARDA); Miller, Marissa A (NIH/NHLBI) [E]; Mark Polizzotto; (b) (6) (b) (6) Proschan, Michael (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Paul Klekotka - Lilly; Harrigan, Rachel (HHS/IOS); Cavan, Reilly; Roger Paredes; (b) (6) Read, Sarah (NIH/NIAID) [E]; Shweta Sharma; Taylor Thompson; (b) (6) (b) (6) Rosenberg, Yves (NIH/NHLBI) [E]; Davey, Victoria (b) (6) Denning, Eileen; Larson, Gregg; Peter Smith, M.D. (Thoracic Surgery); Katharina Krapp; John Rule; Aileen M Ilaria  
**Optional Attendees:** Daniel Dawson Murray; emilia. (b) (6) Lisbeth Jørgensen; Nicole Engen; RH-FP-CHIP-ACTIV3-INSIGHT014; Tierney, John (NIH/NIAID) [E]; Marie Hel eberg, Cate Carey; Vjecha, Michael; Hudson, Fleur; Pett, Sarah; Bitten Aagaard; Charlotte Bjernved Nielsen, Kent P Hassett; Lilian Gonzalez; Andrew G Koustenis; Eccard-Koons, Vanessa (NIH) [C]; Buehn, Molly (NIH) [C]; MacDonald, Leah (NIH) [C]; Ganapathy Gopalrathnam; Janice Evans; Janel e A Sabo; Carlos O Garner - Lilly, Tonya L Combs; Lori J Stephens; Lau, Chuen-Yen (NIH/NIAID) [E]; Herpin, Betsey (NIH/NIAID) [E]; Barrett, Kevin (NIH/NIAID) [E]; Smolskis, Mary (NIH/NIAID) [E]; Engel, Theresa (NIH) [C]; Osborne, Cynthia (NIH) [C]; Simpson, Shelly (NIH) [C]; Vogel, Susan (NIH/NIAID) [E]; Grace, Beth (NIH/NIAID) [C]; Proffitt, Calvin (NIH) [C]; Hohn, Matt (NIH) [C]; (b) (6) McNay, Laura (NIH/NIAID) [E]; Pierson, Jerome (NIH/NIAID) [C]; Mock, Rebecca (NIH/NIAID) [E]; Sega. Raim, Sharon (NIH) [E]; Miller, Tracey (NIH) [C]; Parrish, David (NIH/NIAID) [E]; Galcik, Michael (NIH) [C]; Dighero-Kemp, Bonnie (NIH/NIAID) [C]; Hensley, Lisa (NIH/NIAID) [E]

Stacey Adam is inviting you to a scheduled zoom meeting.

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**From:** Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 9/2/2020 9:28:22 PM  
**To:** Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];  
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];  
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)  
(b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Saran (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria



[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [ (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) Diamond, Michael [ (b) (6) Rose Li [ (b) (6) Dana Carluccio [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [ (b) (6) Dave Frankowski [ (b) (6) Baric, Toni C [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoonoh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [ (b) (6) (b) (6) Reynolds, Lindsey [ (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]

**Subject:** RE: ACTIV Preclinical full working group

Thank you for the update Clint

Joe

**Subject:** Re: ACTIV Preclinical full working group

All –

(b) (4)

Clint

**From:** (b) (6)  
**When:** 10:00 AM - 11:00 AM September 2, 2020  
**Subject:** ACTIV Preclinical full working group  
**Location:** <https://fnih.zoom.us> (b) (6)

Changing time for preclinical WG

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 5/15/2020 7:21:09 PM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Collis]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [ (b) (6) Keith Gottesdiener [ (b) (6) Eric Hughes [ (b) (6) LaVange, Lisa M [ (b) (6) Elliott Levy [ (b) (6) Sandeep Menon [ (b) (6) Amanda Peppercorn [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [ (b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [ (b) (6) Wung, Peter /US [ (b) (6) Karen Lynn Price [ (b) (6) Pamela Tenaerts, M.D. [ (b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8ca9-ehiggs]; Burgess, Timothy [ (b) (6) Beumont-Mauviel, Maria [JRDUS] [ (b) (6) Peeters, Monika [JRDBE] [ (b) (6) Woodfall, Brian [JRDUS] [ (b) (6) Van Heeswijk, Rolf [JRDBE] [ (b) (6)  
**CC:** Mary Biggs [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]  
**Subject:** ACTIV TX-C Initial Master Protocol Subgroup Meeting #19  
**Location:** <https://fnih.zoom.us/> (b) (6)  
**Start:** 5/20/2020 5:00:00 PM  
**End:** 5/20/2020 6:00:00 PM

Show Time As: Tentative

**Required Attendees:** Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]

**Optional Attendees:** Mary Biggs Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

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**From:** Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 7/24/2020 5:25:36 PM  
**To:** Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]  
**Subject:** FW: Summary of the ACTIV Immune Modulator Prioritization Adjudication and Confidentiality Forms  
**Attachments:** 2020-07-22 TX-Immune Modulators Summary.pdf; Therapeutic Clinical Working Group Confidentiality Agreement Individual Template 5-28-2020.docx; Therapeutic Clinical Working Group Confidentiality Agreement Institution Template 5-28-2020.docx

Ellen,

An example of what is going out when we need agreements to review therapeutics.

Joe

**From:** Adam, Stacey (FNIH) [T] <(b) (6)>  
**Sent:** Friday, July 24, 2020 12:57 PM  
**To:** Chen, Helen Q. <(b) (6)> Fessel, Josh (NIH/NHLBI) [E]  
<(b) (6)> Deye, Greg (NIH/NIAID) [E] <(b) (6)> Punturieri, Antonello (NIH/NHLBI) [E]  
<(b) (6)> McNamara, James (NIH/NIAID) [E] <(b) (6)> Wung, Peter /US  
<(b) (6)> Vincent, Michael <(b) (6)> Goff, David (NIH/NHLBI) [E]  
<(b) (6)> Garner, Carl <(b) (6)> Robien, Mark (NIH/NIAID) [E]  
<(b) (6)> Toggias, Alkis (NIH/NIAID) [E] <(b) (6)> Patel, Naimish  
<(b) (6)> Gottesdiener, Keith <(b) (6)> Eric Hughes  
<(b) (6)> Aggarwal, Neil (NIH/NHLBI) [E] <(b) (6)> Levy, Elliot  
<(b) (6)> Rosenberg, Yves (NIH/NHLBI) [E] <(b) (6)> Buchman, Tim (OS/ASPR/BARDA)  
(CTR) <(b) (6)>  
**Cc:** Dana Carluccio <(b) (6)> Rose Li Central Account <(b) (6)>  
Read, Sarah (NIH/NIAID) [E] <(b) (6)> Young, John <(b) (6)> Colvis, Christine  
(NIH/NCATS) [E] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Alvarez, Rosa Maria  
<(b) (6)>  
**Subject:** Summary of the ACTIV Immune Modulator Prioritization Adjudication and Confidentiality Forms

Dear Agent Prioritization Immune Modulator Subteam,

Please find attached the summary of our adjudication meeting on Wednesday. If you have any additions or amendments, please let us know

In addition, based on our last cycle of reviews, the group expressed a desire to request more information for a few compounds that are requesting CDAs to release the data. In order to obtain this information, we will need to sign a CDA with this group to receive the information. Therefore, we will also need each of you (who is not a government employee) to sign a confidentiality agreement with us, so that we can then share the data with you.

Please find attached the template for the confidentiality agreements that we have been using for any of our ACTIV TX-Clinical WG members that needed to view confidential information. You will see that there are two versions of the confidentiality agreement.

- One version is for those individuals who are able to sign this type of agreement on your own behalf.
- One version is for those individuals whose institutions require that the institutional signatory sign on the individual's behalf.

We provide both options upfront as we may not which will apply to each of you.



Please review the confidentiality agreement and send back the signed copy as soon as you can. Once we have all of these signed and the information from the agent teams, we will circulate to the group for final review and decision on that agent. Please note, if you signed one of these for the Antiviral group, it will apply this one as well and you do not need to sign another.

Please return your signed agreement to Helen or myself as soon as you can. If you have any questions, do not hesitate to reach out.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Foundation for the National Institutes of Health  
Direct: (b) (6) Mobile: (b) (6)  
[fnih.org](http://fnih.org)  
11460 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNHI's Pandemic Response Fund to combat COVID-19. [fnih.org/pandemic](http://fnih.org/pandemic)



**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 4/22/2020 1:34:24 AM  
**To:** Eric Hughes [ (b) (6) ] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [ (b) (6) ] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Na mish Patel [ (b) (6) ] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [ (b) (6) ] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [ (b) (6) ] Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [ (b) (6) ]  
**CC:** Elizabeth Kim [ (b) (6) ] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]; Alvarez, Rosa Maria [ (b) (6) ] Salathin, Carla [ (b) (6) ] (b) (6) (b) (6) (b) (6)  
Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [ (b) (6) ]

**Subject:** ACTIV Therapeutics-Clinical Agent Prioritizat on Subgroup Meeting  
**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 4/28/2020 6:00:00 PM  
**End:** 4/28/2020 7:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael  
**Optional Attendees:** Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) (b) (6)  
Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

**Sent:** 6/17/2020 12:42:10 PM

**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Jim Neaton [ (b) (6) ]; Jens Lundgren [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [ (b) (6) ]; Eric Hughes [ (b) (6) ]; Higgs, Elizabeth (NIH/NIAID) [E] [ (b) (6) ]; Goff, David (NIH/NHLBI) [E] [ (b) (6) ]; Nayak, Seema (NIH/NIAID) [E] [ (b) (6) ]; Kozak, Marina (OS/ASPR/BARDA) [ (b) (6) ]; McNay, Laura (NIH/NIAID) [E] [ (b) (6) ]; Tierney, John (NIH/NIAID) [E] [ (b) (6) ]; Aggarwal, Neil (NIH/NHLBI) [E] [ (b) (6) ]; Rosenberg, Yves (NIH/NHLBI) [E] [ (b) (6) ]; Patterson, Amy (NIH/NHLBI) [E] [ (b) (6) ]; Miller, Marissa A (NIH/NHLBI) [E] [ (b) (6) ]; Rachel Harrigan [ (b) (6) ]; Erhardt, William (HHS/IOS) [ (b) (6) ]; Reineck, Lora (NIH/NHLBI) [E] [ (b) (6) ]; [ (b) (6) ]; Gelijns, Annetine [ (b) (6) ]; Mark Polizzotto [ (b) (6) ]; [ (b) (6) ]; Ginny Kan [ (b) (6) ]; Baker, Jason [Jason. (b) (6) ]; Roger Paredes [ (b) (6) ]; Thompson, Taylor, M.D. [TTHOMPSON (b) (6) ]; Babiker, Ab [ (b) (6) ]; Ginde, Adit [ (b) (6) ]; Aileen M Ilaria [ (b) (6) ]; Srinivasan, Badhri [ (b) (6) ]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]

**CC:** Chen, Helen Q. [ (b) (6) ]; Wachtel, Jonathan [ (b) (6) ]; Tountas, Karen (FNIH) [T] [ (b) (6) ]; Desrosiers, Elizabeth A. [ (b) (6) ]; Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Pett, Sarah [ (b) (6) ]; Grace, Beth (NIH/NIAID) [C] [ (b) (6) ]; Barrett, Kevin (NIH/NIAID) [E] [ (b) (6) ]; Denning, Eileen [ (b) (6) ]; Eileen Denning [ (b) (6) ]; Baseler, Beth (NIH) [C] [ (b) (6) ]; Engel, Theresa (NIH) [C] [ (b) (6) ]; Lisbeth Jørgensen [ (b) (6) ]; RH-FP-INSIGHT014-ACTIV3 [nsight014-activ3.rigshospitalet@regionh.dk]; Erhardt, William (HHS/IOS) [ (b) (6) ]; Judith Anne Gallagher [ (b) (6) ]; Kenny, Dermot [ (b) (6) ]

**Subject:** ACTIV-3 Operations Team Meeting

**Attachments:** ACTIV\_TX-Clinical\_ACTIV-3 Operations Team Meeting Agenda\_20200623.pdf

**Location:** [https://fnih.zoom.us/j/ \(b\) \(6\)](https://fnih.zoom.us/j/ (b) (6))

**Start:** 6/23/2020 3:00:00 PM

**End:** 6/23/2020 4:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Jim Neaton; Jens Lundgren; Read, Sarah (NIH/NIAID) [E]; Eric Hughes, Higgs, Elizabeth (NIH/NIAID) [E]; Srinivasan, Badhri; Goff, David (NIH/NHLBI) [E]; Nayak, Seema (NIH/NIAID) [E]; Victoria Davey, Kozak, Marina (OS/ASPR/BARDA); McNay, Laura (NIH/NIAID) [E]; Tierney, John (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; Erhardt, William (OS/ASA/OCIO/DCIO-Ops) (CTR); Reineck, Lora (NIH/NHLBI) [E]; [ (b) (6) ]; Gelijns, Annetine; Mark Polizzotto; Ginny Kan; Baker, Jason; Roger Paredes, Thompson, Taylor, M.D.; Babiker, Ab; Ginde, Adit; Aileen M Ilaria

**Optional Attendees:** Chen, Helen Q.; Wachtel, Jonathan; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Kenny, Dermot; Parker, Ashley (NIH/OD) [E]; Pett, Sarah; Grace, Beth (NIH/NIAID) [C]; Barrett, Kevin (NIH/NIAID) [E]; Denning, Eileen; Eileen Denning; Baseler, Beth (NIH) [C]; Engel, Theresa (NIH) [C]; Lisbeth Jørgensen; RH-FP-INSIGHT014-ACTIV3; Erhardt, William (HHS/IOS); Judith Anne Gallagher

Dear ACTIV-3 Operations Team,

Please find attached the high level agenda for tomorrow. Let me know if you have any additions or amendments.

APAR0000020427-2517074

Thanks,  
Stacey

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**From:** Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 5/8/2020 8:00:21 PM  
**To:** (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];  
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US (b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Louise Pitt (b) (6) (b) (6)  
**CC:** Diamond, Michael (b) (6) Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy (b) (6) Hughes, Eric (b) (6) Jansen, Kathryn (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria (b) (6) Kim, Elizabeth (b) (6) Tolman, Brett (b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes (b) (6) Rose Li (b) (6) Dana Carluccio (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Conson, Samantha

(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg], Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [ (b) (6) Dave Frankowski [ (b) (6)

**Subject:** May 8 ACTIV Preclinical working group ACTION ITEMS

**Attachments:** ACTIV PRECLINICAL\_Animal Model inventory 20200507.xlsx; Antiviral expert names.docx; Small animal models d1 MD.pptx

Dear Preclinical Working Group attendees,

Thank you for an interesting and productive meeting today. It really is a pleasure working with you.

We are working on the minutes, but I wanted to distribute the action items so that you can get started on the items that need your input.

1. Joe and Rosa to send the animal model inventory excel file to the Preclinical working group and to the leads of the Vaccine working group to review. Specific request: ensure that the all columns needed for prioritization and analysis are captured. (It is easier to take columns away versus adding them after we begin collecting data)
2. The Preclinical WG is asked to provide any concerns about proposed members of the in vitro expert panel to Joe by this evening (Saturday afternoon at the latest). If no objections, then Joe will send a letter of invitation to join the ACTIV expert panel and begin to setup an initial meeting.
3. Michael Diamond will draft a 1-2 page preclinical asset review sheet (for expert panel review) before the end of the weekend. Joe will send the draft to the Preclinical WG to provide additions from the animal model working group as well as anyone in the WG. This initial in vitro/ in vivo preclinical asset review sheet will be used as a starting point for the expert panels to modify. We will use this to begin setting up an input form for the needed data by potential sponsors.
4. Industry members of the working group will suggest people with CRO or industry experience but currently non-conflicted positions to the in vivo expert panel. These will be added to the NIH and academic suggestions by Dr Jim Anderson.
5. Jim Anderson and Chris Austin will work to obtain a view into all the NIH data in the publication portal supported by the office of portfolio management.
6. Joe will share the slide from Mike Diamond on the cross subgroup information.

Best regards,

Joe and Rosa

-----Original Appointment-----

**From:** Menetski, Joseph (FNIH) [T]

**Sent:** Tuesday, April 14, 2020 6:48 PM

**To:** (b) (6) (b) (6) (b) (6) Menetski, Joseph (FNIH) [T];

(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis

(NIH/OD) [E]; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]

**Cc:** Diamond, Michael; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Lowy,

Douglas (NIH/NCI) [E]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; A varez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose L; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Louise Pitt (b) (6)

**Subject:** ACTIV Preclinical working group (Friday meeting)

**When:** Friday, May 8, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

**Where:** <https://fnih.zoom.us/> (b) (6)

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 4/22/2020 1:15:24 PM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [ (b) (6) Butterson, Joan [ (b) (6) Collins, Sylva (FDA/CDER) (b) (6) ]; Judy Currier [ (b) (6) De Claro, R. Angelo (FDA/CDER) [ (b) (6) Mark Eisner [ (b) (6) Keith Gottesdiener [ (b) (6) Eric Hughes [ (b) (6) LaVange, Lisa M [ (b) (6) Elliott Levy [ (b) (6) Sandeep Menon [ (b) (6) Amanda Peppercorn [ (b) (6) Proschan, Michael (NIH/NIAID) [E] (b) (6) ; Read, Sarah (NIH/NIAID) [E] (b) (6) Amanda Peppercorn [ (b) (6) Price, Dionne (FDA/CDER) [ (b) (6) Rubin, Daniel B. (FDA/CDER) [ (b) (6) Shen, Yuan Li (FDA/CDER) [ (b) (6) Farley, John (FDA/CDER) [ (b) (6) Goff, David (NIH/NHLBI) [E] [ (b) (6) Vincent, Michael [ (b) (6) (b) (6)  
**CC:** Mary Biggs [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6) Wachtel, Jonathan [ (b) (6) Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [ (b) (6) Wholley, David (FNIH) [T] (b) (6) ; Melencio, Cheryl (FNIH) [T] (b) (6) ; Wung, Peter /US [ (b) (6) Qashu, Felicia (NIH/OD) [E] (b) (6) ]

**Subject:** ACTIV TX-Clinical Master Protocol Subgroup Meeting #6

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 4/23/2020 5:00:00 PM

**End:** 4/23/2020 6:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes, Lisa LaVange, Elliott Levy, Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E], Read, Sarah (NIH/NIAID) [E], Amanda Peppercorn, Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER), Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael

**Optional Attendees:** Mary Biggs Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US; Qashu, Felicia (NIH/OD) [E]

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**Sent:** 5/30/2020 1:17:20 AM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=User3c2f486d]  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Elsaid, Olivia [REDACTED] (b) (6)  
**Subject:** RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30  
**Attachments:** ACTIV Therapeutics\_053020v1.pptx

Hi Francis,

I have pre-emptively modified slide 7 to fit the description below. Please let me know if this makes more sense.

Thanks,  
Stacey

**Stacey J. Adam, PhD**

Director, Cancer

Research Partnerships

Direct [REDACTED] (b) (6) Mobile: [REDACTED] (b) (6)

**From:** Adam, Stacey (FNIH) [T]  
**Sent:** Friday, May 29, 2020 9:13 PM  
**To:** Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)> Gonzalez, Nina <[REDACTED] (b) (6)>  
**Cc:** Wholley, David (FNIH) [T] <[REDACTED] (b) (6)> Freire, Maria (FNIH) [T] <[REDACTED] (b) (6)> Parker, Ashley (NIH/OD) [E] <[REDACTED] (b) (6)> Elsaid, Olivia <[REDACTED] (b) (6)>  
**Subject:** RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi Francis,

Here is what I know specifically from conversations with the companies.

- We know that BMS has ongoing Investigator Initiated Studies (IISs) with Abatacept that are early Phase II. Data not public yet.
- We know that Janssen also has a few preliminary trials, which is why they were getting ready to launch a large Phase 2 RCT of their own before they signed on to ACTIV-1, when we approached them. They had taken their protocol all the way through FDA approval.
- The only one I am not sure of is Cenicriviroc. AbbVie/Allergan have hinted at an IIS, but I would need to confirm. This was one of the R&D Consortium molecules, so I think they had some data to get it on that list.

I could reach out to the companies to see if they will give us more details, but I don't know if we would have it be your meeting with Moncef.

*We can soften the language to say 2 of the 3 have known existing or ongoing Phase II is COVID-19.*

Please let me know if you'd like the slide modified.

Thanks,  
Stacey

**Stacey J. Adam, PhD**

Director, Cancer

Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>

**Sent:** Friday, May 29, 2020 9:02 PM

**To:** Gonzalez, Nina (b) (6)

**Cc:** Adam, Stacey (FNIH) [T] <(b) (6)>, Wholley, David (FNIH) [T] (b) (6), Freire, Maria (FNIH) [T] (b) (6); Parker, Ashley (NIH/OD) [E] (b) (6); Elsaid, Olivia (b) (6)

**Subject:** RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi all,

Thanks, this is an excellent set, though to keep the discussions with Moncef concise, I've moved some of the slides to the Appendix. See current version. I will send this to Janet now too.

One question: when the immunomodulator slide 7 says this:

*All 3 agents have initial Phase II data or are currently running company-sponsored Phase II trials*

What does that mean? Phase II trials for what application?

Francis

**From:** Gonzalez, Nina (b) (6)

**Sent:** Friday, May 29, 2020 8:37 PM

**To:** Collins, Francis (NIH/OD) [E] (b) (6)

**Cc:** Adam, Stacey (FNIH) [T] (b) (6); Wholley, David (FNIH) [T] (b) (6); Freire, Maria (FNIH) [T] (b) (6); Parker, Ashley (NIH/OD) [E] <(b) (6)> Elsaid, Olivia <(b) (6)>

**Subject:** RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi Francis,

See attached the latest version of the slides for the meeting tomorrow.

We'll be on standby for any edits you may have.

Thank you,

Nina

**Nina Gonzalez**

Deloitte Consulting LLP

Tel/Direct: (

(b) (6)

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**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Friday, May 29, 2020 8:32 PM  
**To:** Wholley, David (FNIH) [T] < (b) (6) >  
**Cc:** Adam, Stacey (FNIH) [T] (b) (6); Freire, Maria (FNIH) [T] (b) (6); Gonzalez, Nina (b) (6); Parker, Ashley (NIH/OD) [E] (b) (6)  
**Subject:** [EXT] RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hoping these are coming to me soon, as I may want to do some editing -- and then I wanted to run them past Janet tonight.

FC

**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Friday, May 29, 2020 7:41 PM  
**To:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Cc:** Adam, Stacey (FNIH) [T] < (b) (6) >; Freire, Maria (FNIH) [T] < (b) (6) >; Gonzalez, Nina (b) (6); Parker, Ashley (NIH/OD) [E] (b) (6); Freire, Maria (FNIH) [T] (b) (6)  
**Subject:** RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Have seen and offered a few changes to the complete slide deck. They should be coming back to you as soon as Deloitte makes the changes.

**From:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Sent:** Friday, May 29, 2020 5:59 PM  
**To:** Wholley, David (FNIH) [T] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] (b) (6); Freire, Maria (FNIH) [T] (b) (6); Gonzalez, Nina (b) (6); Parker, Ashley (NIH/OD) [E] < (b) (6) >  
**Subject:** RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note -- has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

APAR0000001307-2517077

Thanks, Francis

**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Friday, May 29, 2020 1:59 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] (b) (6) >; Freire, Maria (FNIH) [T] (b) (6) >; Gonzalez, Nina (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6)  
**Subject:** Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here's the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
  - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
  - ACTIV hiVIG (sponsored by NIAID) – in progress
  - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
  - ACTIV-2\* – Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
  - ACTIV-3\* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
  - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) – (Phase II/III) – projected launch late June
  - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August *(if needed; i.e. if agents are not incorporated into mAb protocols)*
    - \* current priority

[for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)  
[Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
  - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
  - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
  - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS

- Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
- Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
- Protocol is 80% complete
  - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
    - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
  - All three companies have written their sections of the protocols, which are being merged into the master design
- Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- "ACTIV-4" Protocol for anticoagulants
  - Need bullets from NHLBI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS "network of networks" with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley  
 Senior Vice-President, Research Partnerships  
 Foundation for the National Institutes of Health

(b) (6)

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To: Read, Sarah (NIH/NIAID) [E] [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [ (b) (6) Mellors, John W [ (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [ (b) (6) Eisner, Mark [ (b) (6) Gottesdiener, Keith [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) LaVange, Lisa [ (b) (6) Levy, Elliot [ (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish (b) (6) Peppercorn, Amanda [ (b) (6) Poole, Mike [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn [ (b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8f8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dc8c847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [ (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative



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CC: Sorosa, Alex David | (b) (6) Elsaid, Olivia | (b) (6) Chen, Helen Q. | (b) (6) Stratton, Benjamin | (b) (6) Gonzalez, Nina | (b) (6) Alvarez, Rosa | (b) (6) Tolman, Brett | (b) (6) Derek Smith | (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John | (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan | (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Dana Carluccio | (b) (6) Rose Li Central Account | (b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smaldon | (b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; | (b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) | (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bcfd32930-walkerpl]; Bethany Stokes

[ (b) (6) Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]

**Attachments:** ACTIV\_TX-Clinical\_Working Group Meeting Guide\_20201022.pdf

**Start:** 10/22/2020 5:00:00 PM

**End:** 10/22/2020 6:00:00 PM

**Recurrence:** (none)

**Required Attendees:** Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L. Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]

**Optional Attendees:** Derek Smith; Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus, Macone, Erin; Melencio, Cheryl (FNIH) [T]; Saathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Margaret Anderson; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzieski, Andre (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Frerre, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa, Alex David

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today.

Thanks,  
Stacey

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**Sent:** 6/6/2020 3:03:52 AM  
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**CC:** Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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**Subject:** Follow up from ACTIV TX-Clinical Working Group Meeting #9

**Attachments:** 2020-06-04 TX-Clinical WG Meeting Summary.pdf; ACTIV Leadership Team Meeting 20200603 FINAL.pdf; 2020-06-03 ACTIV Leadership Group Meeting Summary Final.pdf

Dear ACTIV TX-Clinical WG,

Thanks for a great discussion yesterday during our meeting. I hope everyone found the updates from the master protocol teams and the mAb Agent Prioritization Subteam helpful. Please find the formal summary of the meeting. If you have any additions or amendments, please contact me.

In addition, please find attached the update slides and the summary from the recent ACTIV Leadership Team meeting. This will provide you with a snapshot overview of what the other working groups are working on right now. I hope this will help to put all of our efforts into perspective with the larger effort.

Thank you again to all of you for all your dedication and hard work!

Enjoy the weekend,  
Stacey

**Stacey J. Adam, PhD**

Director, Cancer

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**on behalf of** Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
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CC:



[T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]

**Subject:** ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, March 18, 2021

**Attachments:** 03.18.21 ACTIV EC and Leadership Team Meeting 20210317\_vFinal.pdf; 03.18.21 ACTIV EC and Leadership Team Meeting\_APPENDIX 20210317 vF.pdf; 2021-02-17 ACTIV Leadership Team and Executive Committee Meeting Summary vF.pdf

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Thursday, March 18, 2021 from 10:30 a.m. to 12:00 p.m. Eastern U.S. Time**. The minutes from the February 17 Executive Committee/Leadership Team call are also attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health  
(b) (6)

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*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*

**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA74284158B86087D08B628E6F-MELENCIOC]  
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[ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes], Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user0fa7bd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; bto man [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; [ (b) (6) Castillejos, Carlos [ (b) (6) FNIH Central Account [ (b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dof75b31b-hallettaa]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolnetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolnetzc]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Sorosa, Alex [ (b) (6) Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; CC: Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Bell, Julie [ (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Caulfield, Anita [ (b) (6) Coan, Amanda [ (b) (6) Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan [ (b) (6) Fuhrer, Nicole [ (b) (6) Giorgi, Sara [ (b) (6) Hoban, Michelle [ (b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide [ (b) (6) Jenkins, Christine S. [ (b) (6) Krack, Kimberly [kimberly]; [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Lever, Susan [susan. [ (b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth [ (b) (6) Perala, Mie [ (b) (6) ]; Protasiewicz, Ann [ (b) (6) Riccobene, Kim [ (b) (6) Riffin, Mary [ (b) (6) ]

Ripley, Nadege [ (b) (6) Schuster, Donna [ (b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togash, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togash m]; Underwood, Nancy [ (b) (6) Zottoli, Jessica (b) (6) Regan, Donna M [ (b) (6) Hamilton, Nancy [ (b) (6) Dana Carluccio [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowydl]

**Subject:** ACTIV Leadership Call #9

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 10/21/2020 1:15:00 PM

**End:** 10/21/2020 2:15:00 PM

**Show Time As:** Tentative

**Required Attendees:** Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauc, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; G bbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Ras, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, He en; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; (b) (6) Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Appell, Evan; Sorosa, Alex; Connelly, Sarah; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Peralta, Mie; Protasiewicz, Ann; Riccobene, Kim; Rigglin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Regan, Donna M; Hamilton, Nancy; Dana Carluccio; (b) (6) ; Lowy, Douglas (NIH/NCI) [E]

Due to an unavoidable conflict for Dr. Collins, it is necessary to move this call from 12:00 p.m. to 9:15 a.m. Thank you.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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**From:** Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]  
**Sent:** 7/3/2020 4:22:05 PM  
**To:** Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]  
**Subject:** Fwd: Notes from Wednesday's ACTIV Leadership Team Meeting  
**Attachments:** 2020-07-01\_ACTIV Leadership Team Meeting Summary FINAL.docx; ATT00001.htm

FYI

**From:** "Wholley, David (FNIH) [T]" <(b) (6)>  
**Date:** July 3, 2020 at 11:56:07 AM EDT  
**To:** "Austin, Christopher (NIH/NCATS) [E]" <(b) (6)>, "Carter, Kara" <(b) (6)>, "Cavaleri, Marco" <(b) (6)>, "Cihlar, Tomas" <(b) (6)>, "Collins, Francis (NIH/OD) [E]" <(b) (6)>, "Corey, Larry" <(b) (6)>, Culp, Michelle (NIH/OD) [E]" <(b) (6)>, "Disbrow, Gary" <(b) (6)>, "Dolsten, Mikael" <(b) (6)>, "Erbelding, Emily (NIH/NIAID) [E]" <(b) (6)>, "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)>, "Freire, Maria (FNIH) [T]" <(b) (6)>, "Gadbois, Ellen (NIH/OD) [E]" <(b) (6)>, "Gibbons, Gary (NIH/NHLBI) [E]" <(b) (6)>, "Hudson, Thomas" <(b) (6)>, "James, Stephanie (FNIH) [T]" <(b) (6)>, "Johnson, Robert" <(b) (6)>, "Kramer, Lynn" <(b) (6)>, "Lane, Cliff" <(b) (6)>, "Lepore, John" <(b) (6)>, "Marks, Peter" <(b) (6)>, "Marston, Hilary (NIH/NIAID) [E]" <(b) (6)>, "Mascola, John (NIH/VRC) [E]" <(b) (6)>, "Meeker, David" <(b) (6)>, "Menetski, Joseph (FNIH) [T]" <(b) (6)>, "Messonnier, Nancy (CDC/DDID/NCIRD/OD)" <(b) (6)>, "Pandya, Hitesh" <(b) (6)>, "Pangalos, Mene" <(b) (6)>, "Pao, William" <(b) (6)>, "Parker, Ashley" <(b) (6)>, "Paul, Steve" <(b) (6)>, "Perimutter, Roger" <(b) (6)>, "Plenge, Robert" <(b) (6)>, "Plump, Andy" <(b) (6)>, Rachel Ramoni <(b) (6)>, "Rasi, Guido" <(b) (6)>, "Reed, John" <(b) (6)>, "Reese, David" <(b) (6)>, "Rouse, Doris" <(b) (6)>, "Santos, Michael (FNIH) [T]" <(b) (6)>, "Skovronsky, Daniel" <(b) (6)>, "Stein, Peter (FDA/CDER)" <(b) (6)>, "Stoffels, Paul" <(b) (6)>, "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)>, "Talley, Michael" <(b) (6)>, "Tsai, John" <(b) (6)>, "Vessey, Rupert" <(b) (6)>, "Virgin, Skip" <(b) (6)>, "Woodcock, Janet (FDA/CDER)" <(b) (6)>, "Young, John" <(b) (6)>, "Colvis, Christine (NIH/NCATS) [E]" <(b) (6)>, "Desrosiers, Betsy" <(b) (6)>, "Hughes, Eric" <(b) (6)>, "Jansen, Kathrin" <(b) (6)>, "Kurilla, Michael (NIH/NCATS) [E]" <(b) (6)>, "Lowy, Douglas (NCI)" <(b) (6)>, "Read, Sarah (NIH/NIAID) [E]" <(b) (6)>, "Young, John" <(b) (6)>, "Mallory, Raburn" <(b) (6)>  
**Cc:** "Adam, Stacey (FNIH) [T]" <(b) (6)>, "Alvarez, Rosa" <(b) (6)>, "Anderson, Margaret" <(b) (6)>, "Chen, Helen" <(b) (6)>, oelsaid <(b) (6)>, "Gonzalez, Nina" <(b) (6)>, "James, Stephanie" <(b) (6)>, "Menetski, Joseph (FNIH) [T]" <(b) (6)>, "Santos, Michael" <(b) (6)>, "Stratton, Ben" <(b) (6)>, "Tolman, Brett" <(b) (6)>

< (b) (6) "Tountas, Karen (FNIH) [T]" (b) (6) "Wachtel, Jonathan"  
(b) (6) >, "Anderson, James (NIH/OD) [E]" (b) (6) >, "Austin,  
Christopher (NIH/NCATS) [E]" < (b) (6) "Burklow, John (NIH/OD) [E]"  
(b) (6) , "Castillejos, Carlos" (b) (6) >, "Hallett, Adrienne (NIH/OD) [E]"  
(b) (6) , "Lane, Cliff (NIH/NIAID) [E]" (b) (6) >, "Myles, Renate  
(NIH/OD) [E]" (b) (6) >, "Wolinetz, Carrie (NIH/OD) [E]" (b) (6) >

**Subject: Notes from Wednesday's ACTIV Leadership Team Meeting**

Dear All:

Please see the notes from our teleconference on Wednesday, July 1. The action items are listed at the top of the document and so are not being sent out separately.

Please let me know any additional comments or questions regarding these notes.

Thank you again for all your support of and contributions to ACTIV. Have a happy Fourth of July weekend!

David Wholley

**From:** Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]

**Sent:** 11/1/2020 5:02:19 PM

**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp];  
(b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];  
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];  
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) ] (b) (6)  
Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiena]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)  
**CC:** Diamond, Michael [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim,



While not unanimous, more people were able to make the 5<sup>th</sup> at 10am. We will go over the discussion at the Executive committee meeting, future strategic topics and then our normal reviews.

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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**From:** Emilio Emini [REDACTED] (b) (6)  
**Sent:** 5/17/2020 3:04:11 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**CC:** Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]  
**Subject:** RE: URGENT, need your response: Making your ACTIV Participation Public

Dear Francis et al.—Yes, please feel free to include my name....

Emilio

**Emilio A. Emini, Ph.D., FCPP, FAAM**  
Director  
TIS and HIV Programs  
Bill & Melinda Gates Foundation

**From:** Collins, Francis (NIH/OD) [E] <[REDACTED]> (b) (6)  
**Sent:** Saturday, May 16, 2020 6:02 PM  
**To:** Collins, Francis (NIH/OD) [E] <[REDACTED]> (b) (6)  
**Cc:** Myles, Renate (NIH/OD) [E] <[REDACTED]> (b) (6); Meltzer, Abbey (FNIH) [T] <[REDACTED]> (b) (6); Wholley, David (FNIH) [T] <[REDACTED]> (b) (6)  
**Subject:** URGENT, need your response: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this follow up and increasingly urgent message is for you, even though your address was in the bcc line! We have heard from almost all of the ACTIV Working Group participants, and so far all have been happy to have their names listed in the ACTIV web site. But we still haven't heard from YOU.

Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please don't delay further, and send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 5 p.m. ET tomorrow, Sunday May 17.**

Thanks,  
Francis

Francis S. Collins, MD, PhD  
NIH Director



**From:** Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]

**Sent:** 6/3/2020 12:03:52 PM

**To:** (b) (6) (b) (6) (b) (6) (b) (6)  
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];  
 (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
 (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];  
 (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US [ (b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Punturien, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]

**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [ (b) (6) Kim, Elizabeth [ (b) (6) Tolman, Brett [ (b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) Diamond, Michael

(b) (6) Rose Li (b) (6) Dana Carluccio  
(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange  
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel];  
Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];  
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi  
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=Sbbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D  
(b) (6) Dave Frankowski (b) (6) Lowy, Douglas (NIH/NCI) [E]  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowydl]; Florence, Clint (NIH/NIAID)  
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Louise Pitt  
(b) (6) (b) (6) Nancy Haigwood [/o=ExchangeLabs/ou=Exchange  
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwood.oh];  
Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]

**Subject:** ACTIV Preclinical working group (Friday meeting)

**Location:** <https://fnih.zoom.us/j/> (b) (6)

**Start:** 4/24/2020 3:00:00 PM

**End:** 4/24/2020 4:00:00 PM

**Show Time As:** Tentative

**Recurrence:** Weekly  
every Friday from 11:00 AM to 12:00 PM

**Required Attendees:** (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];  
(b) (6) , Adams, Peter (OS/ASPR/BARDA), Rao, Srinivas /US; Anderson, James (NIH/OD)  
[E]; Qashu, Felicia (NIH/OD) [E]; Tomas Cinlar; Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E];  
Fessel, Josh (NIH/NHLBI) [E]

**Optional Attendees:** Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine  
(NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Doug as  
(NCI), Read, Sarah (NIH/NIAID) [E], Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T];  
James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachter, Jonathan; Prabhavathi  
Fernandes; Diamond, Michael; Rose Li, Dana Carluccio, Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha  
(NIH/NCATS) [E], Gonzalez, Nina, Simon, Dina (NIH/OD) [C], Burrus-Shaw, Cyndi (NIH/OD) [E], Rodriguez, Robin D;  
Dave Frankowski, Lowy, Douglas (NIH/NCI) [E], Florence, Clint (NIH/NIAID) [E], Louise Pitt (b) (6)  
Nancy Haigwood, Hild, Sheri (NIH/OD) [E]

Holding time

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**From:** John Lepore [ (b) (6) ]  
**Sent:** 4/9/2020 12:38:28 AM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**CC:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]  
**Subject:** RE: URGENT: Invitation to join the Vaccines Working Group of the COVID PPP

Dear Francis -

Thank you very much for sponsoring this critical initiative and for enabling GSK to contribute.

Please do reach out if you see any other way we could be of help.

With best wishes -

John

**John Lepore**  
**SVP, Head of Research**

**GSK**  
1250 S. Collegeville Road, Mail Code UP4-4400, Collegeville, PA 19426, US  
**Email** (b) (6)  
**Tel** (b) (6)  
**Mobile**



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**From:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Sent:** Wednesday, April 08, 2020 8:27 PM  
**To:** Emmanuel Hanon < (b) (6) >  
**Cc:** Melencio, Cheryl (FNIH) [T] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > John Lepore < (b) (6) >  
**Subject:** URGENT: Invitation to join the Vaccines Working Group of the COVID PPP

EXTERNAL

Dear Dr. Hanon,

Addressing the COVID-19 pandemic is an urgent priority for the entire biomedical research community. Appropriately, the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond. But there is still no proven treatment, and safe and effective vaccines are many months away.

APAR0000012710-2517086

NIH has been working at the forefront of addressing the crisis, including rapidly launching its own clinical trials of therapeutics and a vaccine candidate. But given the seriousness of this global public health crisis, it is time to broaden the response and create a focused public-private partnership with FDA, industry, and academic scientists to further accelerate progress against COVID and the threat of future pandemics. This past Friday I led an initial discussion convened by the Foundation for the National Institutes of Health (FNIH) to decide on the initial research agenda for the partnership. There was broad support from all sectors for this model — with some harkening back to a similar partnership that led to the development of antivirals for HIV/AIDS many years ago. Inspired by the shared embrace of a call to action, we are immediately launching efforts to collaborate in four key areas—accelerating preclinical therapeutic development, optimizing clinical therapeutic development, coordinating clinical trials capacity, and supporting effective vaccine development. Those four areas, and a summary of the meeting, are described in the attached document.

Each area will be powered by a nimble Working Group that includes appropriate domain expertise drawn from among our stakeholders. **You have been recommended to us by John Lepore as a member of the Vaccines Working Group.** The primary objective of this working group is to provide a collaborative framework for advancing vaccine development. I expect this will require a significant investment of your time when I know time is scarce. But these very serious circumstances call for full dedication to action from us all. I am personally committed to doing everything possible to support the execution of this partnership, and would be deeply appreciative if you will contribute your talents to this important effort.

Please direct your response to this invitation by Thursday April 9 (tomorrow! sorry this is such short notice) at 12pm EDT to Cheryl Melencio (b) (6). You may send any questions to Mike Santos (b) (6) at FNIH. A calendar invitation to the initial meeting of the Working Group will be sent out shortly after the response deadline.

I look forward to working with you on this critical effort.

Best,  
Francis S. Collins, M.D., Ph.D.  
Director, NIH

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**From:** Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]  
**Sent:** 4/9/2020 12:21:37 AM  
**To:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]  
**CC:** Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]  
**Subject:** RE: GSK follow up on FNIH COVID call

I'll do it.

**From:** Wholley, David (FNIH) [T] <(b) (6)>  
**Sent:** Wednesday, April 8, 2020 7:36 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>; Lane, Cliff (NIH/NIAID) [E] <(b) (6)>; Erbeling, Emily (NIH/NIAID) [E] <(b) (6)>; Austin, Christopher (NIH/NCATS) [E] <(b) (6)>  
**Cc:** Tabak, Lawrence (NIH/OD) [E] <(b) (6)>; Parker, Ashley (NIH/OD) [E] <(b) (6)>; Melencio, Cheryl (FNIH) [T] <(b) (6)>; Santos, Michael (FNIH) [T] <(b) (6)>  
**Subject:** FW: GSK follow up on FNIH COVID call

FYI We'll add them to the list. Francis, do you want to send out the invitation emails? We can forward yours if you don't have time.

**From:** John Lepore (b) (6)  
**Sent:** Wednesday, April 8, 2020 5:55 PM  
**To:** Wholley, David (FNIH) [T] <(b) (6)>  
**Cc:** Santos, Michael (FNIH) [T] (b) (6); David Payne (b) (6); Emmanuel Hanon (b) (6); Amanda Peppercorn (b) (6); >  
**Subject:** RE: GSK follow up on FNIH COVID call

Hi David -

Writing e-mail to you as I received this...

Yes, we are very keen to participate with the following suggestions:

- **David Payne**, head of our infectious disease research group, to participate on the preclinical workstream. David is an industry veteran with extensive drug discovery experience across novel anti-bacterials and anti-virals and I think can contribute importantly to discussions about optimizing assays, reagents and models.
- **Amanda Peppercorn**, physician-scientist with extensive experience in clinical trials and and regulatory interactions for anti-viral drug-development; has led our influenza program, among others. To participate on the clinical trials workstream.



- **Emmanuel Hanon** - head of vaccines R&D in GSK, to participate on the vaccines workstream.

I've copied all 3 on this e-mail so you can contact them directly

If you would please keep me copied in to minutes from the various workstreams, I'd really appreciate that.

If there is anything else GSK could help with, please do reach out.

Thanks so much for your help -

John

**From:** Wholley, David (FNIH) [T] <(b) (6)>  
**Sent:** Wednesday, April 08, 2020 5:48 PM  
**To:** John Lepore (b) (6)  
**Cc:** Santos, Michael (FNIH) [T] (b) (6) >  
**Subject:** RE: GSK follow up on FNIH COVID call

EXTERNAL

Hi John, I don't think I have seen your suggestions for the COVID committees yet, just checking We'd love to have input from your leadership, particularly on vaccines and therapeutics groups. Thanks, David

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**To:** Bozzette, Sam (NIH/NCATS) [E] [ (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adams;4];  
 Butterson, Joan [ (b) (6) De Claro, R. Angelo (FDA/CDER) [ (b) (6) ];  
 Draghia-Akli, Ruxandra [ (b) (6) Gottesdiener, Keith [ (b) (6) Eric Hughes  
 [ (b) (6) Judy Currier [ (b) (6) Kim, Elizabeth [ (b) (6)  
 LaVange, Lisa [ (b) (6) Levy, Elliot [ (b) (6) Mellors, John W [ (b) (6) Menon,  
 Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange  
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];  
 Peppercorn, Amanda [ (b) (6) Poole, Mike [ (b) (6) Proschan,  
 Michael (NIH/NIAID) [E] [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [ (b) (6) Santos,  
 Michael (FNIH) [T] [ (b) (6) Shen, Yuan Li (FDA/CDER) [ (b) (6) Stein, Peter  
 (FDA/CDER) [ (b) (6) Wholley, David (FNIH) [T] [ (b) (6) Buchman, Tim  
 (OS/ASPR/BARDA) (CTR) [ (b) (6) Collins, Sylva (FDA/CDER) [ (b) (6) Amanda  
 Peppercorn [ (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [ (b) (6) Koroshetz,  
 Walter (NIH/NINDS) [E] [ (b) (6) Timothy Burgess [ (b) (6) Reineck, Lora  
 (NIH/NHLBI) [E] [ (b) (6) Aggarwal, Neil (NIH/NHLBI) [E] [ (b) (6) Rosenberg, Yves  
 (NIH/NHLBI) [E] [ (b) (6) .gov]; Goff, David (NIH/NHLBI) [E] [ (b) (6) Brown, Jeremy  
 (NIH/NINDS) [E] [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [ (b) (6) Culp, Michelle  
 (NIH/OD) [E] [ (b) (6) ; Jacqueline Kirchner [ (b) (6) ; Beigel, John  
 (NIH) [E] [ (b) (6) Phillips, L Revell CIV DTRA RD (USA) [ (b) (6) Petrovick, Martha -  
 0449 - MITLL [ (b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E]  
 [ (b) (6) Larry Tsai [tsai. (b) (6) Wung, Peter K [ (b) (6) Bozzette,  
 Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Patel, Naimish  
 [ (b) (6) Garner, Carl [ (b) (6)  
**CC:** Colvis, Christine (NIH/NCATS) [E] [ (b) (6) Jansen, Kathrin [ (b) (6) Lowy,  
 Douglas (NCI) [ (b) (6) ]; Young, John [ (b) (6) Biggs, Mary [ (b) (6)  
 Butcher, Tina [ (b) (6) Demarcus [ (b) (6) Macone, Erin  
 [ (b) (6) Melencio, Cheryl (FNIH) [T] [ (b) (6) Salathin, Carla  
 [ (b) (6) Menetski, Joseph (FNIH) [T] [ (b) (6) Dana Carluccio  
 [ (b) (6) Rose Li Central Account [ (b) (6) Lucas Smalldon  
 [ (b) (6) Mollica, Linda /US  
 [ (b) (6) Qashu, Felicia (NIH/OD) [E] [ (b) (6) Patterson, Amy (NIH/NHLBI) [E]  
 [ (b) (6) Rubin, Daniel B. (FDA/CDER) [ (b) (6) Marston, Hilary (NIH/NIAID) [E]  
 [ (b) (6) Chen, Helen Q. [ (b) (6) Hoots, W. Keith (NIH/NHLBI) [E]  
 [ (b) (6) Groesch, Mary (NIH/NHLBI) [E] [ (b) (6) Shipp, Alan (NIH/NHLBI) [E]  
 (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E] [ (b) (6) Hone, David M (Dave) CIV  
 DTRA J9 (USA) [ (b) (6) Reiser, Ronald B CTR USARMY DOD JPEO CBRND (USA)  
 [ronald. (b) (6) Walker, Paula (NIH/NINDS) [E] [ (b) (6) Sorosa, Alex David  
 [ (b) (6) Lumsden, Joanne (NIH/NCATS) [C] [ (b) (6) ]; Lerner, Andrea (NIH/NIAID)  
 [E] [ (b) (6) Embry, Alan (NIH/NIAID) [E] [ (b) (6) ]; Dally, Nicolle  
 [ (b) (6) Atkinson, Jane (NIH/NCATS) [E] [ (b) (6) Boucher,  
 Cynthia (NIH/NCATS) [E] [ (b) (6)

**Start:** 4/8/2021 5:00:00 PM  
**End:** 4/8/2021 6:00:00 PM

**Recurrence:** (none)

**Required Attendees:** Bozzette, Sam (NIH/NCATS) [E]; Patel, Naimish; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Gottesdiener, Keith; Hughes, Eric; Judy Currier, Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil

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(NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]; Larry Tsai, Wung, Peter K

**Optional Attendees:** Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Menetski, Joseph (FNIH) [T]; Dana Carluccio; Rose Li Centra Account; Lucas Sma Idon; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, H lary (NIH/NIAID) [E]; Chen, Helen; Hoots, W. Kerth (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex; Lumsden, Joanne (NIH/NCATS) [C]; Lerner, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Dally, Nicole; (b) (6) Atkinson, Jane (NIH/NCATS) [E]; Boucher, Cynthia (NIH/NCATS) [E]

**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 5/29/2020 12:26:44 AM  
**To:** Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [ (b) (6) ]; LaVange, Lisa M [ (b) (6) ]; Sandeep Menon [ (b) (6) ]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proschan]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [ (b) (6) ]; (b) (6) [ (b) (6) ]; (b) (6) [ (b) (6) ]; (b) (6) [ (b) (6) ]; Eron, Joe [ (b) (6) ]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner [ (b) (6) ]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]  
**CC:** Demarcus [ (b) (6) ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) ]; Elizabeth Kim [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jhoanna Roa [ (b) (6) ]; Eron, Joseph J Jr [ (b) (6) ]; Smith, David [ (b) (6) ]; Paul Klekotka [ (b) (6) ]; Ajay Nirula [ (b) (6) ]; Lucas Smalldon [ (b) (6) ]; Rose Li Central Account [ (b) (6) ]; Dana Carluccio [ (b) (6) ]; Chen, Helen Q. [ (b) (6) ]  
**Subject:** Summary from ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting  
**Attachments:** 2020-05-27\_TX-Clinical\_WG\_ACTIV-2\_Writing Team\_mAb\_SC\_Summary.pdf

Dear ACTIV-2 Writing Team and ACTIV mAb Steering Committee,

Thank you so much for a very productive meeting with the ACTIV-2 team yesterday. I think we were able to make a lot of head way on the outstanding protocol decisions which helped the team refine further today on their call.

For your reference, please find attached the formal summary to the meeting. If you have additions or amendments, please contact me and I will make them.

Thanks,  
Stacey

**Stacey J. Adam, PhD**

Director, Cancer

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**Sent:** 9/6/2020 3:13:39 AM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fid]; Draghia-Akli, Ruxandra [ (b) (6) Eisner, Mark [ (b) (6) Gottesdiener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) LaVange, Lisa [ (b) (6) Levy, Elliot [ (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Patel, Naimish (b) (6) Peppercorn, Amanda [ (b) (6) Poole, Mike [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [ (b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dc8c847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [ (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative



Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) | (b) (6) Petrovick, Martha - 0449 - MITLL | (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7248415bb86087d08b628e6f-melencioc]; Salathin, Carla | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio | (b) (6) Rose Li Central Account | (b) (6) Anderson, Margaret | (b) (6) Lucas Smalldon | (b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; (b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bcfd32930-walkerp1]

**Subject:** Summary of the ACTIV Therapeutics-Clinical Working Group Meeting 09/03/2020

**Attachments:** 2020-09-03\_TX-Clinical WG Meeting\_Summary.pdf

Dear ACTIV Therapeutics-Clinical WG and Guests,

Please find attached the summary of the meeting on Thursday. We truly appreciate your attendance. We also greatly thank our guest from NHLBI for their presentation!

Have a great hol day weekend!

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Foundation for the National Institutes of Health  
Direct: (b) (6) | Mobile: (b) (6)  
[fnih.org](http://fnih.org)  
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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: [fnih.org/pandemic](http://fnih.org/pandemic)



**From:** Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 5/7/2020 9:06:17 PM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [ (b) (6) Keith Gottesdiener [ (b) (6) Eric Hughes [ (b) (6) LaVange, Lisa M [ (b) (6) Elliott Levy [ (b) (6) Sandeep Menon [ (b) (6) Amanda Peppercorn [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [ (b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [ (b) (6) Wung, Peter /US [ (b) (6) Karen Lynn Price [ (b) (6) Pamela Tenaerts, M.D. [ (b) (6) Scott Berry [ (b) (6) Angus, Derek [ (b) (6) Meredith Buxton [ (b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]  
**CC:** Mary Biggs [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Tountas Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Goffney, Robertta [ (b) (6)  
**Subject:** ACTIV TX-Clinical Master Protocol Subgroup Meeting #17  
**Location:** <https://fnih.zoom.us/> (b) (6)  
**Start:** 5/15/2020 5:00:00 PM  
**End:** 5/15/2020 6:00:00 PM  
**Show Time As:** Tentative

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**Required Attendees:** Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Caro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes, Lisa LaVange, Elliott Levy; Sandeep Menon, Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER), Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Scott Berry; Angus, Derek; Meredith Buxton; Patterson, Amy (NIH/NHLBI) [E]

**Optional Attendees:** Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Goffeney, Robertta

Stacey Adam is inviting you to a scheduled Zoom meeting.

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**From:** Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]  
**Sent:** 7/9/2020 5:17:41 PM  
**To:** Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponeim]  
**Subject:** RE: website updates for ACTIV

This should've been included – I added this one to the list and sent to Renate.

Thanks!  
Ashley

**From:** Brodd, Lauren (NIH/OD) [E] < > (b) (6)  
**Sent:** Thursday, July 9, 2020 12:20 PM  
**To:** Parker, Ashley (NIH/OD) [E] < > (b) (6)  
**Subject:** RE: website updates for ACTIV

Another thing I just noticed is that under the *News and Blogs* section of the website, the July 8 announcement about the clinical trials network was added, but not the July 1 announcement about the Vaccine WG paper. There might be a reason for not adding the paper and therefore we don't need it on our list, but just wanted to flag it.

**From:** Brodd, Lauren (NIH/OD) [E]  
**Sent:** Thursday, July 9, 2020 12:05 PM  
**To:** Parker, Ashley (NIH/OD) [E] < > (b) (6)  
**Subject:** RE: website updates for ACTIV

Hi Ashley,

Revised list based on our discussion, for your review before it goes to Renate.

Please make the following changes to the ACTIV website:

- Add Moderna and Novavax to list of Leadership Organizations
- Clinical Trial Capacity Working Group (on leadership page):
  - For the charge, change "NIH ICs, industry, and other organizations" to "*NIH ICs, industry, and contract research organizations*"
- Vaccine Working Group (on leadership page):
  - For the charge, change "with a master protocol trial for prevention of disease" to "*by supporting harmonized clinical efficacy trials*"
  - On roster, change title for Tonya L Villafana PhD, MPH to *Vice President, Global Franchise Head, infection*

Once finalized, let me know if you plan to send to Renate or you would like me to send.

Thanks!

Lauren

**From:** Brodd, Lauren (NIH/OD) [E]  
**Sent:** Thursday, July 9, 2020 8:39 AM  
**To:** Parker, Ashley (NIH/OD) [E] (b) (6)  
**Subject:** RE: website updates for ACTIV

Hi Ashley,

I asked Cheryl about Gregory Glenn, and she had followed up with him again a few weeks ago (6/25) when we asked previously but never heard. She said this morning:

- *I have not heard back from him I will copied Mike Santos on the last reminder I will send another one and ask Mike if he could reach out.*

So I will let you know if I hear from her about his response.

The first bullet on my list for Renate was "Add Moderna and Novavax to list of Leadership Organizations" I saw your comment in your email below about adding them, so is there somewhere else they should also be added (aside from Leadership Organizations)?

Regarding Cat Lutz, she is not on the leadership meeting slides so we don't need to add Jax to the website. I just wanted to double check about that because the BMGF is on the website but not on the slides.

Thanks!

**From:** Parker, Ashley (NIH/OD) [E] (b) (6) >  
**Sent:** Thursday, July 9, 2020 8:22 AM  
**To:** Brodd, Lauren (NIH/OD) [E] (b) (6)  
**Subject:** RE: website updates for ACTIV

Hi Lauren,

Comments in blue below.

Let's add: include Moderna and Novavax on the list of companies.

Thanks,  
Ashley

**From:** Brodd, Lauren (NIH/OD) [E] (b) (6) >  
**Sent:** Thursday, July 9, 2020 7:50 AM  
**To:** Parker, Ashley (NIH/OD) [E] < (b) (6)  
**Subject:** website updates for ACTIV

Hi Ashley,

I double checked my list of website issues, and if we are going to email Renate about the companies as in the chain below, then here is what I have:

- Add Moderna and Novavax to list of Leadership Organizations (if agreed upon as indicated below).
- Vaccine Working Group:
  - Add Gregory Glenn (if he gives permission; let me know if you want me to follow up with Cheryl directly) Yes, please ask Cheryl if she heard anything I think she was planning to follow up



- Change title for Tonya L Villafana PhD, MPH to Vice President, Global Franchise Head, Infection Corrency

Other possibilities:

- As we previously discussed, the charge of the Preclinical WG is listed on the website as: *Create an integrated preclinical framework to evaluate existing drugs and drug candidates that require preclinical evaluation for both repurposing and development of novel therapeutics.*
  - This is still the language listed in the leadership slides, so not sure if this has been “officially” updated with language we would use for the website, but the JAMA paper lists as: The Preclinical Working Group was charged to standardize and share preclinical evaluation resources and methods and accelerate testing of candidate therapies and vaccines to support entry into clinical trials. We can ask Joe Meneteski to confirm – I will write him.
  - Note: there are slight differences in wording between the JAMA paper and the website, although the Preclinical WG varies the most. Let me know if you want to see a comparison for the other WG between the website and JAMA paper.
- Wasn't sure the final decision on this, but Cat Lutz is on preclinical WG, so should Jackson Labs be listed as a nonprofit partner- should this be verified with FNIH before they are added? According to The Jackson Laboratory website: JAX is an independent, 501(c)3 nonprofit biomedical research institution that seeks to...Is Cat Lutz on the leadership team? If not, JAX should not be listed.
  - I can double check my list but I think that is the only other difference between WG members and leadership organizations (aside from academic institutions).

Wanted to get your thoughts on the list so it is organized to go to Renate today depending on the decision about the companies

Thanks,

Lauren

**From:** Parker, Ashley (NIH/OD) [E] (b) (6)  
**Sent:** Thursday, July 9, 2020 12:54 AM  
**To:** Santos, Michael (FNIH) [T] (b) (6) >  
**Cc:** Wholley, David (FNIH) [T] < (b) (6)  
**Subject:** Re: Invitation from Francis Collins to join COVID public-private partnership

Hi Mike,

Yes, I raised this a few weeks ago and agree we should add Moderna and Novavax to the list of companies on the website. I can alert our team to get this updated tomorrow and maybe you can alert Abbey/Greta to update on the FNIH website?

The last time I checked, Cheryl was still waiting to hear back from the Novavax rep on the vaccines WG, Gregory Glenn to see if he approved to be listed on the website — have you heard anything?

Also, there's time to think about inviting Tal Zaks or a rep from Moderna to the leadership team meetings but I'll leave that decision to David and the war room!

Thanks,  
Ashley

On Jul 8, 2020, at 11:08 PM, Santos, Michael (FNIH) [T] (b) (6) > wrote:

Hi Ashley,

I remember there was some discussion about which organizations are listed on the ACTIV webpage after you raised the question of Moderna and Novavax not being listed, and what the criteria are for that.

Tal Zaks of Moderna is requesting that they be listed (see below). Given that OWS just made a big investment in Novavax, it may make sense to have their participation listed as well, as its absence may be noticed at this point (and like Moderna they have been regular participants in Vaccines meetings).

Although it would lead to some inconsistencies in the principles of who is listed, at this point it might be most straightforward just to add those two companies. What do you think? If there are any other steps, of course I'm happy to help out.

Thanks,  
Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Tal Zaks (b) (6)  
**Sent:** Wednesday, July 8, 2020 10:56 PM  
**To:** Santos, Michael (FNIH) [T] (b) (6)  
**Subject:** Re: Invitation from Francis Collins to join COVID public-private partnership

Dear Michael,

I'm following on this email of a while ago, as it has recently been brought to my attention that we (Moderna) are not listed as a participating organization on the ACTIV website, despite having been active participants since you had kindly invited us back in April.

Can you please help me understand whether this is an oversight of communications or some other omission on my part? If so, can I ask how can we correct it? We are proud to be part of this effort.

Thanks!

Tal

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**From:** "Santos, Michael (FNIH) [T]" (b) (6) >  
**Date:** Sunday, April 19, 2020 at 1:53 PM  
**To:** Stephane Bancel (b) (6)  
**Cc:** "Mascola, John (NIH/VRC) [E]" (b) (6), "Tolman, Brett" (b) (6), Tal Zaks (b) (6)  
**Subject:** RE: Invitation from Francis Collins to join COVID public-private partnership

Dear Stephane,

Thanks much for your quick reply. We're delighted to have Moderna represented in the Working Group

Tal: We will follow up with additional information and calendar invitations to the Working Group meetings. Please don't hesitate to reach out with any questions. We're looking forward to working with you.

Best regards,  
Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Stephane Bancel (b) (6)  
**Sent:** Sunday, April 19, 2020 1:50 PM  
**To:** Santos, Michael (FNIH) [T] <(b) (6)>  
**Cc:** Mascola, John (NIH/VRC) [E] (b) (6) >; Tolman, Brett (b) (6) >; Tal Zaks (b) (6)  
**Subject:** Re: Invitation from Francis Collins to join COVID public-private partnership

Dear Mike, thanks a lot for the invitation. We appreciate it given our already great partnership with NIAID on the mRNA-1273 clinical development. We are finalizing our Phase 2 plans.

Tal Zaks, our CMO leads our SARS CoV 2 vaccine development. I think he will be the right person to participate in that group.

He is copied here

Cheers

stephane

---

**From:** "Santos, Michael (FNIH) [T]" <(b) (6)>  
**Date:** Sunday, April 19, 2020 at 12:09 PM  
**To:** Stephane Bancel (b) (6)  
**Cc:** John Mascola (b) (6) "Tolman, Brett" (b) (6) >  
**Subject:** Invitation from Francis Collins to join COVID public-private partnership

Dear Stephane,

If you have not already, you will soon receive an invitation from Francis Collins to join the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership, and in particular the Vaccines Working Group, which John Mascola is also a member of.

The next meeting of the Vaccines Working Group is tomorrow (Monday, Apr 20) at 9am ET; a calendar invitation follows. Further information and materials are attached. We hope you will be able to participate. Please do not hesitate to reach out with any questions, and we would be happy to provide additional information.

Best regards,  
Mike

**Michael Santos, PhD**  
Associate Vice President, Science  
Foundation for the National Institutes of Health  
(b) (6) fnih.org  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852  
<image001.jpg> <image002.jpg> <image003.jpg> <image004.jpg>

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**From:** Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]  
**Sent:** 7/11/2020 3:27:44 AM  
**To:** (b) (6) (b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron.cohen]; (b) (6) (b) (6) .com; Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; (b) (6) (b) (6) (b) (6) Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda]; (b) (6) Hamilton, Hollie (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa422d0576cc-Hollie.Hamil]; (b) (6) (b) (6) Ledgerwood, Julie (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dc9f31ded594eff8ac506d2c4103c15-ledgerwood]; (b) (6) (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Mascola, John (NIH/VR) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; (b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56f6be4598a57b423d484dcf9f-offit.email]; Merlin Robb [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6442891c7f7b404486500d6ed251a686-MerlinRobb]; (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7248415bb86087d08b628e6f-melencioc]; Laurent Humeau [ (b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wachtel, Jonathan (b) (6) Hotez, Peter Jay [ (b) (6) (b) (6) Tal Zaks [ (b) (6) (b) (6) Greg Glenn [ (b) (6) (b) (6) Gebo, Kelly (NIH/OD) [G] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=009cf99ae63f4f71b5b1204a73ded609-geboka]; Jacqueline Miller [ (b) (6) Tolman, Brett [ (b) (6) (b) (6) (b) (6) Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Soriano Osejo, Douglas [ (b) (6) Stratton, Benjamin [ (b) (6) Sitar, Sandra (NIH/VR) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

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 [ (b) (6) Murray, Jeannie [ (b) (6)

**Subject:** Notes from the Vaccines Clinical Trials Sub-Group meeting

**Attachments:** 2020-07-09 Vaccines Clinical Trials Sub-Group meeting Notes.docx; 2020-07-09 Vaccines Clinical Trials Sub-Group meeting.pptx; Abbreviated ACTIV NETWORK Survey.docx; Abbreviated ACTIV SITE Survey.docx

Dear Vaccines Clinical Trials Sub-Group members,

Thank you for your participation in Thursday's engaged discussion. The notes and meeting materials are attached. The conversation covered a lot of topics, and please send any additional thoughts or comments.

In addition, many of you are aware of the clinical trial network and site capacity survey that the ACTIV Clinical Trial Capacity Working Group has run. That group would like to update their questions for the next round of surveying to better capture information relevant for vaccine trials. Anyone who is interested is welcome to review the attached questions and send recommended adds/changes/drops from those lists.

As always, please reach out with any questions or suggestions.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Thursday, July 9, 2020 9:18 AM  
**Subject:** Agenda for today's Vaccines Clinical Trials Sub-Group meeting

Dear Vaccines Clinical Trials Sub-Group members,

We're looking forward to our meeting today (Thursday) at 1pm ET (10am PT / 7pm CEST).

The main agenda topic is what the implications of the first vaccine licensure will be for the overall vaccine development effort. Larry and Paula will introduce the topic and lay out some questions for group discussion.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science | Foundation for the National Institutes of Health



**From:** Santos, Michael (FNIH) [T]  
**Sent:** Tuesday, July 7, 2020 6:19 PM  
**Subject:** Notes and Materials from the Vaccines Clinical Trials Sub-Group meeting

Dear Vaccines Clinical Trials Sub-Group members,

Thank you for your participation in our meeting, and particular thanks to Emily and Kathy for leading the discussion.

Attached please find the meeting notes and presentation. In addition, please recall the request from Emily and Kathy to the group:

- They would like to hear from developers as you discuss with regulators your plans for testing your vaccines in pregnant women.

Please don't hesitate to reach out with any additions, edits, or questions.

Best regards,  
Brett and Mike

**Michael Santos, PhD**  
Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Wednesday, July 1, 2020 12:17 PM  
**Subject:** Agenda for the Vaccines Clinical Trials Sub-Group meeting tomorrow

Dear Vaccines Clinical Trials Sub-Group members,

We're looking forward to our meeting tomorrow (Thursday) at 10am ET (7am PT / 4pm CEST). The main agenda topic is testing of COVID vaccines in pregnant women. This is a topic that Kathy Neuzil and Emily Erbelding have been working on, and they will present and lead the discussion- they would like feedback from the group on various options.

As always, please reach out with any questions or input.

Best regards,  
Brett and Mike

**Michael Santos, PhD**  
Associate Vice President, Science  
**Foundation for the National Institutes of Health**  
(b) (6) [fnih.org](https://fnih.org)  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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CC: (b) (6) (b) (6) Wholley, David (FNIH) [T]  
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**Location:** <https://nih.zoom.us/> (b) (6)

**Start:** 10/21/2020 2:15:00 PM

**End:** 10/21/2020 3:00:00 PM

**Show Time As:** Tentative

**Recurrence:** (none)  
every Wednesday from 10:00 AM to 11:00 AM

**Required Attendees:** (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6)  
(b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6)  
(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];  
(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];  
Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];  
Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

**Optional Attendees:** (b) (6) (b) (6) Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth, Tolman, Brett, Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio, Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski, Baric, Toni C, Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin, Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah

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**From:** (b) (6) | (b) (6)  
**Sent:** 5/13/2020 11:19:30 AM  
**To:** Wolinetz, Carne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]  
**CC:** Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]  
**Subject:** Fwd: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time  
**Attachments:** Agenda ACTIV EC Meet ng #1 5-13-20.docx; ATT00001.htm; Proposal for ACTIV leadership-vF 051220.pdf; ATT00002.htm

For 8am ACTIV EC Meeting if you want to read ahead.

Thanks,  
Ashley

Begin forwarded message:

**From:** "Wholley, David (FNIH) [T]" <(b) (6)>  
**Date:** May 12, 2020 at 9:57:04 PM EDT  
**To:** "Collins, Francis (NIH/OD) [E]" (b) (6) "Dolsten, Mikael" (b) (6)  
(b) (6) "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)> "Gibbons, Gary (NIH/NHLB) [E]" <(b) (6)> "Pao, William" (b) (6) "Stoffels, Paul [JJCUS]" (b) (6) "Woodcock, Janet (FDA/CDER)" (b) (6)  
"Colvis, Christine (NIH/NCATS) [E]" (b) (6) "Desrosiers, Betsy" (b) (6)  
(b) (6) "Hughes, Eric" <(b) (6)> "Jansen, Kathrin" (b) (6)  
(b) (6) "Kurilla, Michael (NIH/NCATS) [E]" (b) (6) "Lowy, Douglas (NIH/NCI) [E]" <(b) (6)> "Read, Sarah (NIH/NIAID) [E]" (b) (6) >  
"Young, John" (b) (6) "Menetski, Joseph (FNIH) [T]" (b) (6) ,  
"Adam, Stacey (FNIH) [T]" (b) (6) "Tountas, Karen (FNIH) [T]" (b) (6) >,  
"Santos, Michael (FNIH) [T]" (b) (6) "Freire, Maria (FNIH) [T]" (b) (6) ,  
"Tabak, Lawrence (NIH/OD) [E]" (b) (6) "Lane, Cliff (NIH/NIAID) [E]" (b) (6)  
(b) (6) "Parker, Ashley (NIH/OD) [E]" <(b) (6)> "Anderson, James (NIH/OD) [E]" (b) (6) "Austin, Christopher (NIH/NCATS) [E]" (b) (6)  
(b) (6) "Wolf-Rodda, Julie (FNIH) [T]" (b) (6) "Gonzalez, Nina" (b) (6)  
**Cc:** "Melencio, Cheryl (FNIH) [T]" (b) (6) "Wood, Gretchen (NIH/OD) [E]" (b) (6)  
**Subject:** Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:  
Please see attached the agenda for our meeting tomorrow morning (via Zoom) and a copy of the letter from the Therapeutics- Clinical Working Group you received earlier today, for our discussion.

Please let Joe Menetski or Cheryl Melencio know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

**David Wholley**  
**Senior Vice-President, Research Partnerships**  
**Foundation for the National Institutes of Health**  
**(b) (6)**

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*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*

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**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA74284158B86087D08B628E6F-MELENCIOC]  
**Sent:** 6/3/2020 11:37:25 PM  
**To:** Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**Subject:** RE: Updated Master email list  
**Attachments:** ACTIV Working Group Rosters - MASTER.xlsx

Is this what you want?

**Cheryl Melencio**

Administrative Manager, Research Partnerships  
Foundation for the National Institutes of Health

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**From:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Sent:** Wednesday, June 3, 2020 5:59 PM  
**To:** Melencio, Cheryl (FNIH) [T] <(b) (6)>  
**Subject:** RE: Updated Master email list

Thanks, Cheryl! Can I also have the updated spreadsheet that the FNIH COMMs group has with names and titles? No rush.

---

**From:** Melencio, Cheryl (FNIH) [T] <(b) (6)>  
**Sent:** Wednesday, June 3, 2020 5:35 PM  
**To:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Subject:** Updated Master email list

Hi Ashley

Here is the spread sheet updated today with David Reese, Tomas Cihlar (who will be attending leadership team meetings for William Lee, Gilead) and Kara Cater added to Industry and master email list. I have also added Tonya Villafana, AstraZeneca to Vaccines Working Group.

Cheryl

**Cheryl Melencio**

Administrative Manager, Research Partnerships  
Foundation for the National Institutes of Health

(b) (6)

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**From:** Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]

**Sent:** 2/11/2021 7:58:52 PM

**To:** (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowy]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell (b) (6) (b) (6) (b) (6) Cavaleri Marco (b) (6) mmdavis [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user87932049] (b) (6) Greg Glenn (b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; (b) (6) (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56f8be4598a57b423d484dcf9f-offit.email], (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) (b) (6) Tal Zaks (b) (6)

**CC:** Tolman, Brett [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; (b) (6) Hopps, Markay (b) (6) Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; (b) (6) Jeneffer Haynes (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; (b) (6) Isabel Ramsey (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Dieffenbach, Carl (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94acc37973d346fa98dfe16cd1bf7013-cdieffenba]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisei]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T]

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 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffab2bf06a684c9ea822683392719418-frd3]; Bloom  
 PhD, Jesse D (b) (6) (b) (6) Christopher Murray [ (b) (6) pennym  
 [ (b) (6) Alex Sigal [ (b) (6) Ho, David D. [ (b) (6) edu]

**Subject:** Slides from today's ACTIV Vaccines Working Group meeting

Hi all,

Thanks again to Trevor and Jesse for their insightful presentations and to everyone who participated in the meeting. Trevor and Jesse have kindly made their slides available at:

- <https://bedford.io/talks/sars-cov-2-molecular-evolution-activ/#/> (advance with space-bar or arrows)
- [https://slides.com/jbloom/sars-cov-2\\_activ](https://slides.com/jbloom/sars-cov-2_activ)

We will be following up with meeting notes, and will send an invite for our next meeting as soon as we can.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Tuesday, February 9, 2021 5:54 PM  
**Subject:** Agenda for the next ACTIV Vaccines Working Group meeting (Thurs, 11 Feb)

Dear Vaccines Working Group members,

We're looking forward to our next meeting, Thursday at 11:30am ET / 8:30am PT / 5:30pm CET. Please note that this meeting is scheduled for 75 min to allow for more discussion.

The topic for this meeting (and planned subsequent meetings) is the evolution of viral variants and the implications for vaccines. For our meeting Thursday, Jesse Bloom and Trevor Bedford of Fred Hutch will join us to present on the genetics of the epidemic and predictive analytics, followed by discussion during which we welcome participants to share the activities that their organizations are undertaking in response.

As always, please reach out with any questions or suggestions.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Sunday, December 13, 2020 7:11 PM  
**Subject:** Agenda for the next ACTIV Vaccines Working Group meeting (Monday, 14 Dec)

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Monday) at 12pm ET / 9am PT / 6pm CET.

The main agenda item for tomorrow is discussion of potential approaches to evaluate the impact of vaccines on transmission. This topic was presented and discussed at the 18 Nov meeting of the Vaccines Clinical Trials Sub-Group. If you were unable to join that meeting (or to refresh your memory), the notes with presentation materials embedded are attached.

If we have additional time after that discussion, we may discuss Working Group member perspectives on the other topics that have been discussed recently in the Clinical Trials Sub-Group: the potential for blinded cross-over within studies (30 Nov, notes attached) and evaluating vaccines in immunocompromised populations (10 Dec, notes still to come).

If you cannot join the meeting but would like to provide input on any of the topics above, please send it to us prior to Wednesday, when Doug will be reporting on behalf of the group to the ACTIV Leadership Team.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science, Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Wednesday, November 18, 2020 7:13 PM  
**Subject:** Notes from the ACTIV Vaccines Working Group meeting

Dear Vaccines Working Group members,

With apologies for the delay, attached are notes and the single slide from last week's Vaccines Working Group meeting.

After the meeting, the Working Group and Sub-Group leadership aligned on the immediate priorities for discussion. Those begin today with the Vaccine Clinical Trial Sub-Group's meeting on evaluating the impact of vaccines on transmission. Topics prioritized for subsequent discussions include potential blinded cross-over for ongoing phase 3 trials, preparing for the possibility of vaccine efficacy varying by platform/product, and evaluating vaccines in immunocompromised populations. Invitations for meetings on those topics will be sent soon.

As always, we welcome addition comments and questions.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Tuesday, November 10, 2020 1:33 PM  
**Subject:** Agenda for tomorrow's ACTIV Vaccines Working Group meeting

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Wednesday) at 1pm ET / 10am PT / 7pm CET. We scheduled this meeting last week without knowledge of yesterday's exciting announcement, and are delighted to be re-convening this group at such an auspicious time.

As we described below, the agenda for tomorrow is an open discussion of the priorities for vaccines in addition to the licensure studies that the Vaccines Working Group or the Clinical Trials Sub-Group should consider. Some members of the group have already proposed a few ideas, and all members of the group are invited to make additional suggestions and weigh in on the potential opportunities. After the meeting we will prioritize next steps.

If you cannot attend tomorrow's meeting, as always please feel free to submit ideas in advance that we can share on your behalf or send feedback on the notes afterwards.

Best regards,  
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]

**Sent:** Friday, November 6, 2020 1:01 PM

**Subject:** Next ACTIV Vaccines Working Group meeting: Weds, 11 Nov

Dear Vaccines Working Group members,

As you may recall from the summer, we agreed to stop regular meetings of the Vaccines Working Group and reconvene as needed. Our next meeting will be Wednesday, 11 Nov, at 1pm ET (10am PT / 7pm CET).

We've been requested by ACTIV leadership to have a discussion about the priorities for vaccines in addition to the licensure studies. The Vaccines Clinical Trials Sub-Group has had previous meetings on the topics of evaluation in pregnant and pediatric populations, and is planning upcoming conversations about studying impact on transmission and evaluation in immunocompromised populations, as well as a discussion of the potential application of expanded access protocols.

At our next Working Group meeting, we would appreciate input on those and other potential priorities for discussion within the group. We are looking forward to your thoughts, and as always appreciate any questions or suggestions.

Best regards,  
Brett and Mike

**Michael Santos, PhD**  
Associate Vice President, Science  
Foundation for the National Institutes of Health  
(b) (6) [fnih.org](https://fnih.org)  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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**From:** Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]  
**Sent:** 5/7/2020 3:19:46 AM  
**To:** (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowy];  
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**CC:** (b) (6) Tal Zaks [ (b) (6) Tolman, Brett [ (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj];  
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(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron\_cohen], Douguuih, Macaya [JRDUS] [ (b) (6) Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Gilbert PhD, Peter B [ (b) (6) Paul Gillard [ (b) (6) (b) (6) Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda], Gurunathan, Sanjay /US [ (b) (6) Hamilton, Holli (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5aaa422d0576cc-Holli.Hamit];  
(b) (6) Ledgerwood, Julie (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dc9f31ded594eff8ac506d2c4103c15-ledgerwood], Leyssen, Maarten [JRDNL] [ (b) (6) Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com]; Robb, Merlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17bbdb1e858542e7b5959ec7aeb7679a-mrobb.hivre]; (b) (6) Michael Watson (x) [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis];  
(b) (6) (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [ (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Kim, Elizabeth [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Stratton, Benjamin [ (b) (6)

**Subject:** REVIEW REQUESTED. Covid-19 human challenge model perspective outline; also Vaccines WG meeting notes

**Attachments:** SARS-CoV-2 Controlled Human Infection Model in Support of Preventive Vaccines Outline.docx; controlled human infection model references.zip; 2020-05-05 Working Group meeting Summary Notes.docx

Dear Vaccines Working Group (and cc'ing other Sub-Group members),

Thank you for your participation in yesterday's Vaccines Working Group meeting. Summary notes kindly prepared by the science writer that supports our group are attached. If you have any additions or edits, please feel free to pass them along.

As we discussed at the meeting, an important new deliverable for our Working Group is a perspective on the scientific and operational obstacles for developing a COVID-19 human challenge model on a relevant timescale. A small team from the Vaccine Clinical Trials Sub-Group has taken on that responsibility, with our gratitude.

**Please review the attached outline.** The team has a particular question about how much substantiation of the points being made is necessary. The team is also contemplating which audiences to target and the best ways to reach them. **If you have suggestions or feedback on the outline, or perspectives on these questions, please share them with us.** Existing papers on this topic are attached in the zip file for your reference. This will be an important agenda topic at our next Working Group meeting on Monday, May 11, 12pm ET (9am PT / 6pm CEST).

We look forward to continued engagement as we forge ahead on the path to support accelerated vaccine development. Please reach out anytime with questions or suggestions.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]

**Sent:** Tuesday, May 5, 2020 2:44 AM

**Subject:** Agenda and Materials for ACTIV Vaccines Working Group meeting: Today, 5 May

Dear Vaccines Working Group,

We are looking forward to our next Vaccines Working Group meeting with you, today (Tuesday) at 12pm ET (9am PT / 6pm CEST). The key agenda items for our meeting are:

- Review new mandates for the Working Group
- Discuss pathways to approval/authorization using correlates and other evidence
- Share ACTIV external communications approach



The slides that we will use during the meeting are attached, with some additional slides drawn from the presentation Marion Gruber shared (attached in full in Friday's notes) in an appendix for reference.

We also want to share an update related to the first agenda item. The Vaccines Clinical Trials Sub-Group met for the first time yesterday (Monday). Much as we anticipate the master protocol trial doing, we rapidly enrolled participants (though perhaps with limited informed consent) in this Sub-Group; the roster as of today is attached, with some additional invitations pending. We have also attached the notes from that meeting.

As always, please do not hesitate to reach out with any input or questions.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Sunday, May 3, 2020 5:45 PM  
**Subject:** Vaccines Working Group important update: Clinical Trial plans

Dear Vaccines Working Group,

Yesterday evening there was an exciting expansion of the opportunity for the Vaccines Working Group to contribute to accelerating vaccine development. We learned that there will be US government funding for a master protocol phase 2/3 adaptive vaccine efficacy trial, with provisions to add and drop vaccine candidate arms over time.

The Clinical Trial Sub-Group (slight name change) will be tasked with supporting this master protocol trial, including the protocol and the networks/sites implementation. The goal is to have this trial ready to start by July 1, though there may be an opportunity to start in June if the work can be completed by then.

This is a significant expansion of scope for the Sub-Group. Given the magnitude of this responsibility, we will be asking for additional representation on the Sub-Group and pulling in expertise, including some of the master protocols experts that have been writing the ACTIV therapeutics protocols. The first meeting of the Sub-Group is tomorrow at 10am ET (7am PT / 4pm CEST).

We will also discuss this at the Vaccines Working Group meeting on Tuesday at 12pm ET (9am PT / 6pm CEST). Please don't hesitate to reach out with any questions.

Best regards,  
Mike, for the Vaccines Working Group

Michael Santos, PhD  
Associate Vice President, Science  
Foundation for the National Institutes of Health  
(b) (6) [fnih.org](https://fnih.org)  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Stay at the forefront of FNIH news: [fnih.org/newsletter](https://fnih.org/newsletter)

**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 6/9/2020 1:10:32 AM  
**To:** Jim Neaton [ (b) (6) ] Jens Lundgren [ (b) (6) ] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [ (b) (6) ] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Srinivasan, Badhri [ (b) (6) ] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Tierney, John (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61553b35beb7479789a06defda628627-jtierney]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [ (b) (6) ] William Erhardt [ (b) (6) ] Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; (b) (6) Gelijns, Annetine [ (b) (6) ] Mark Polizzotto [ (b) (6) ] Ginny Kan [ (b) (6) ] Baker, Jason [ (b) (6) ] Roger Paredes [ (b) (6) ] Thompson, Taylor, M.D. [ (b) (6) ] Babiker, Ab [ (b) (6) ]  
**CC:** Chen, Helen Q. [ (b) (6) ] Wachtel, Jonathan [ (b) (6) ] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A. [ (b) (6) ] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkuril a]; Kenny, Dermot [ (b) (6) ] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Pett, Sarah [ (b) (6) ] Grace, Beth (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]; Barrett, Kevin (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrett2]; Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.ccbrr]  
**Subject:** ACTIV-3 Operations Team Meeting  
**Attachments:** ACTIV\_TX-Clinical\_ACTIV-3 Operations Team Meeting Agenda\_20200609.pdf; INSIGHT014\_ACTIV3\_protocol\_v0.4\_8June2020.pdf  
**Location:** https://fnih.zoom. (b) (6)  
**Start:** 6/9/2020 3:00:00 PM  
**End:** 6/9/2020 3:45:00 PM  
**Show Time As:** Tentative

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**Required Attendees:** Jim Neaton; Jens Lundgren; Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Higgs, Elizabeth (NIH/NIAID) [E]; Srinivasan, Badhri; Goff, David (NIH/NHLBI) [E]; Nayak, Seema (NIH/NIAID) [E]; Victoria Davey, Kozak, Marina (OS/ASPR/BARDA); McNay, Laura (NIH/NIAID) [E]; Tierney, John (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; Reineck, Lora (NIH/NHLBI) [E], (b) (6) Gelijns, Annetine, Mark Polizzotto; Ginny Kan; Baker, Jason; Roger Paredes; Thompson, Taylor, M.D.; Babiker, Ab

**Optional Attendees:** Chen, Helen Q., Wachtel, Jonathan; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Kenny, Dermot; Parker, Ashley (NIH/OD) [E]; Pett, Sarah; Grace, Beth (NIH/NIAID) [C]; Barrett, Kevin (NIH/NIAID) [E]; Denning, Eileen

Dear ACTIV-3 Operations Team,

Please find attached the agenda for tomorrow's call and the current version of the ACTIV-3/TICO protocol. Please note that we are shortening the meeting by 15 minutes tomorrow to give those speaking and facilitating at the mAb Summit time to get organized and join that call a little early.

Thanks,  
Stacey

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**Sent:** 10/21/2020 2:18:54 PM  
**To:** (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai], (b) (6)  
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6) Puntuneri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)  
**CC:** (b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa72428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Saran (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [ (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) Diamond, Michael [ (b) (6) Rose Li [ (b) (6) Dana Carluccio [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [ (b) (6) Dave Frankowski [ (b) (6) Baric, Toni C [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [ (b) (6) Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Shadya Sanders (b) (6)

**Subject:** RE: ACTIV Preclinical full working group

We are running a little late on the LT, coming in a minute or 2.

Joe

-----Original Appointment-----

**From:** Menetski, Joseph (FNIH) [T]

**Sent:** Tuesday, April 14, 2020 6:43 PM

**To:** (b) (6) (b) (6) Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E];

(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)

Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter

(OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM

USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E];

(b) (6)

**Cc:** (b) (6) (b) (6) Wholley, David (FNIH) [T]; Austin, Christopher

(NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen,

Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T];

Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth;

Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique

(NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina, Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi

(NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint

(NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk,

Harrison; Mason, Stephen; Connelly, Sarah; Shadya Sanders

**Subject:** ACTIV Preclinical full working group

**When:** Wednesday, October 21, 2020 10 15 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

**Where:** <https://fnih.zoom.us> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us>, (b) (6)

**From:** Santos, Michael (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]  
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(b) (6) (b) (6) Ledgerwood, Julie (NIH/NIAID) [E]  
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(b) (6) (b) (6) Lowy, Douglas (NIH/NCI) [E]  
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[ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marovich, Mary  
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Mascola, John  
(NIH/VRCA) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Nelson Michael  
[ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha];  
(b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Offit, Paul  
[ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56f6be4598a57b423d484dcf9f-offit.email]; Merlin Robb  
[ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6442891c7f7b404486500d6ed251a686-MerlinRobb];  
(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)  
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7248415bb86087d08b628e6f-melencioc]; Laurent Humeau  
[ (b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.  
(CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Parker, Ashley (NIH/OD) [E]  
[ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wachtel, Jonathan  
(b) (6) Hotez, Peter Jay [ (b) (6) (b) (6) Tal Zaks  
[ (b) (6) (b) (6) Greg Glenn [ (b) (6)  
(b) (6) Gebo, Kelly (NIH/OD) [G] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=009cf99ae63f4f71b5b1204a73ded609-geboka]; Jacqueline Miller  
[ (b) (6) François P Roman [ (b) (6) Culp, Michelle (NIH/OD) [E]  
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(CDC/DDID/NCEZID/DVBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffe35bbdbfbfd495f97712313bedcaecc-ZMT0]; McNamara, Lucy Alexandra  
(CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94d2e362b03243568fa31c3d23550095-xdf4]; Goldstein, Jason  
(CDC/DDID/NCEZID/DSR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2f414dc157843bba7369a63dfde3e5e-fex0]; Schully, Sheri (NIH/OD) [E]  
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(CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=d2f43022aeb34b44a905a094631f56ff-Matt Hepbur]; Najaf Shah  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=322773c4fb274ec5ba1d7c204c58d9f1-MichaelChoy] Gorman, Richard  
 (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=9fa34dbee5794c34b94ee2a55c9dc51e-Richard.Gor]; Johnson, Robert  
 (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Buchbinder, Susan  
 (DPH) [ (b) (6) mmdavis [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user87932049]; (b) (6) Haynes, Barton  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aeb9a0d9b96c-NAR5]; HSchuite@its.jnj.com;  
 Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan Se]; Tartaglia, Jim /US  
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 CC: btolman [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt], Austin, Sarah  
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 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e781b1f84a4f878583062a6ae87017-sitars]; Tong, Tina (NIH/NIAID)  
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 [ (b) (6) Isabel Ramsey [ (b) (6) Sridhar, Saranya /US  
 [ (b) (6) Brian Rosen [ (b) (6) Cheryl Keech [ (b) (6) Sadoff,  
 Jerald [JRDUS] [ (b) (6) Michael, Nelson [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=05b9ca6b24634974b7aeb3fcaead1623-nmichael.hi]; Kayvon Modjarrad  
 [ (b) (6) Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative  
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonnd];  
 (b) (6) (b) (6) Shannon Devine [ (b) (6) Long, Jemma  
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a70a85bdc0c41ac95a0257ea3f252ba-jlong]

**Subject:** ACTIV Vaccines Clinical Trials Sub-Group Meeting

**Location:** <https://fnih.zoom.us/j/> (b) (6)

**Start:** 1/15/2021 7:00:00 PM

End: 1/15/2021 8:00:00 PM

Show Time As: Tentative

**Required Attendees:** (b) (6) (b) (6) (b) (6) Cohen, Myron; (b) (6) Gruber, Erbeling, Emily (NIH/NIAID) [E]; Marion (FDA/CBER); (b) (6) Hamilton, Holli (OS/ASPR/BARDA); (b) (6) Ledgerwood, Julie (NIH/NIAID) [E]; (b) (6) Lowy, Douglas (NIH/NCI) [E]; Marks, Peter (FDA/CBER); Marovich, Mary (NIH/NIAID) [E]; Mascola, John (NIH/VRC) [E]; Nelson Michael; (b) (6) il; Kathleen Neuzil; Offit, Paul; Merin Robb; (b) (6) Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Laurent Humeau; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Parker, Ashley (NIH/OD) [E]; Wachtel, Jonathan; Hotez, Peter Jay; (b) (6) Tal Zaks; (b) (6) Greg Glenn; (b) (6) Gebo, Kelly (NIH/OD) [G]; Jacqueline Miller; François P Roman; Culp, Michelle (NIH/OD) [E]; Martin, Stacey (CDC/DDID/NCEZID/DVBD); McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD); Goldstein, Jason (CDC/DDID/NCEZID/DSR); Schully, Sheri (NIH/OD) [E]; Sotr, Mark (CDC/DDID/NCIRD/DVD); Arvin, Ann; Hepburn, Matt (HHS/IOS); Najaf Shah; Michael Choy; Gorman, Richard (OS/ASPR/BARDA); Johnson, Robert (OS/ASPR/BARDA); Buchbinder, Susan (DPH); (b) (6) (b) (6) Haynes, Barton; (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD); (b) (6) Seals, Jonathan (OS/ASPR/BARDA); Tartaglia, Jim /US; (b) (6) Rotrosen, Danie. (NIH/NIAID) [E]; Tog as, Alkis (NIH/NIAID) [E]

**Optional Attendees:** Tolman, Brett; (b) (6) (b) (6) (b) (6) Johnson, Maureen (NIH/NCI) [E]; Kozlowski, Mary (NIH/NCI) [C]; Austin, Sarah (NIH/NIAID) [E]; Soriano Osejo, Douglas; Sitar, Sandra (NIH/VRC) [C]; Tong, Tina (NIH/NIAID) [E]; Kurilla, Michael (NIH/NCATS) [E]; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Isabel Ramsey; Sridhar, Saranya /US; Brian Rosen; Cheryl Keech; Sadoff, Jerald [JRDUS]; Michael, Nelson; Kayvon Modjarrad; Marston, Hilary (NIH/NIAID) [E]; (b) (6) (b) (6) Shannon Devine; Long, Jemma (NIH/NIAID) [E]

Topic: ACTIV Vaccines Clinical Trials Sub-Group Meeting

Time: Jan 15, 2021 02:00 PM Eastern Time (US and Canada)

Join Zoom Meeting

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US (Chicago)

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US (San Jose)

US (San Jose)

Meeting ID: (b) (6)

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(b) (6)

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**From:** Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
**Sent:** 5/15/2020 1:24:33 AM  
**To:** Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**Subject:** FW: Woodcock summary of current trials  
**Attachments:** jwnationalCOVID19therapeutics pptx

You asked me earlier about the list of 21 mAb companies Janet was referring to. See slide 8 from this deck FC distributed Tuesday, think that is it.

**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Sent:** Tuesday, May 12, 2020 9:43 PM  
**To:** Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Anderson, James (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)>  
**Subject:** Woodcock summary of current trials

Interesting Inventory from Janet...

**From:** Woodcock, Janet <(b) (6)>  
**Sent:** Tuesday, May 12, 2020 9:38 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Yes you can share. It's a bit out of date. As I said I'm doing a deeper dive on convalescent plasma and the neutralizing MoAbs. Should have soon. Need to fill in detail of all planned DOD and NIH studies. Should get to that this week. Jw

---

**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Date:** May 12, 2020 at 8:48:22 PM EDT  
**To:** Woodcock, Janet <(b) (6)>  
**Subject:** RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Hi Janet,

I just got to this e-mail (it's been that kind of day). Wow, there is a LOT of useful information here. May I share with ACTIV leadership?

Francis

**From:** Woodcock, Janet <(b) (6)>  
**Sent:** Tuesday, May 12, 2020 5:01 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Subject:** FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Sent:** Tuesday, May 12, 2020 1:31 PM  
**To:** Woodcock, Janet (b) (6)  
**Subject:** RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

5 pm? 301-641-0104 if you can. Otherwise after 7 pm is good

**From:** Woodcock, Janet (b) (6)  
**Sent:** Tuesday, May 12, 2020 1:08 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

No have to brief higher ups. Later better. Jwv

**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Date:** May 12, 2020 at 12:49:32 PM EDT  
**To:** Woodcock, Janet (b) (6)  
**Subject:** RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Yes, I would like that. Can you do 3:30?

**From:** Woodcock, Janet (b) (6)  
**Sent:** Tuesday, May 12, 2020 11:28 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Can we discuss before tomorrow? jw

**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Tuesday, May 12, 2020 10:46 AM  
**To:** Collins, Francis S (NIH) (b) (6) >; Stoffels, Paul [JJCUS] (b) (6) ; Fauci, Anthony S (NIH) (b) (6) >; Gibbons, Gary H (NIH) (b) (6) >; Woodcock, Janet (b) (6) Pao, William (b) (6) Dolsten, Mikael (b) (6)  
**Cc:** Colvis, Christine M (NIH) (b) (6) >; Desrosiers, Betsy (b) (6) . Hughes, Eric (b) (6) Read, Sarah W (NIH) (b) (6) Jansen, Kathrin (b) (6) Kurilla, Michael G (NIH) (b) (6) ; Lowy, Douglas R (NIH) (b) (6) Young, John (b) (6) >; Freire, Maria C (NIH) <(b) (6)> Tabak, Lawrence A (NIH) <(b) (6)> Lane, Henry C (NIH) (b) (6) Parker, Ashley S (NIH) <(b) (6)> >; Anderson, James M (NIH) (b) (6) Austin, Christopher P (NIH) <(b) (6)> Wolinetz, Carrie D (NIH) <(b) (6)>  
**Subject:** FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Dear ACTIV Executive Committee Members:

Please see the attached letter from the ACTIV Therapeutics-Clinical Working Group received this morning, for consideration on tomorrow morning's Executive Committee teleconference. While we expect the proposals contained herein will be one major topic of discussion, the purpose of the meeting is to hear from all of the Working Group co-chairs (copied on this note) regarding what is working and where they may be facing challenges in ACTIV, and jointly discuss strategy moving forward.

David

**From:** Adam, Stacey (FNIH) [T] (b) (6)  
**Sent:** Tuesday, May 12, 2020 9:52 AM  
**To:** Wholley, David (FNIH) [T] (b) (6) >  
**Cc:** Read, Sarah (NIH/NIAID) [E] (b) (6) . Eric Hughes (b) (6) >; Carlos O Garner  
(b) (6) >; Judy Currier (b) (6) >; Keith Gottesdiener  
(b) (6) Amanda Peppercorn (b) (6) . Stein, Peter (FDA/CDER)  
< (b) (6) ; Higgs, Elizabeth (NIH/NIAID) [E] (b) (6)  
**Subject:** Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Hi David,

Please find attached a letter from the Therapeutics-Clinical Working Group to the ACTIV Executive Committee for their consideration. Overall, the letter is meant to relate some broad challenges and issues that the Therapeutics-Clinical group thinks the ACTIV PPP is facing, as well as some very specific requests for assistance from the ACTIV EC for our team.

Please relay this to the ACTIV EC for their review. Our group would welcome any feedback they have.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Foundation for the National Institutes of Health  
Direct: (b) (6) | Mobile: (b) (6)  
[fnaa.org](http://fnaa.org)  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: [fnih.org/pandemic](http://fnih.org/pandemic)



**From:** Eron, Joseph J Jr | (b) (6)  
**Sent:** 5/22/2020 1:17:21 AM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes (b) (6); LaVange, Lisa M (b) (6); Sandeep Menon (b) (6); Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price (b) (6); Wohl, David A (b) (6); Fischer, William A. II (b) (6); Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6); Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li (b) (6); Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]  
**CC:** DeMarcus, Forrest (b) (6); Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan (b) (6); Elizabeth Kim (b) (6); Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa (b) (6); Smith, David (b) (6); Paul Klekotka (b) (6); Ajay Nirula (b) (6); Elsaid, Olivia (b) (6); Robert Jan Benschoep (b) (6); Lei Shen (b) (6); Chen, Helen Q. (b) (6)  
**Subject:** RE: Notes from the ACTIV TX-Clinical mAb Outpatient WT Meeting-3  
**Attachments:** ACTIV\_Therapeutics-Clinical\_ACTIV TX-Clinical mAb Outpatient WT Meeting-3\_20May2020\_Key TakeawaysJE.pdf

Stats insight super informative

For the summary I think there are some decisions that we made – that were supported by the group

My comments are attached in the PDF

Joe Eron MD

Professor of Medicine

University of North Carolina at Chapel Hill

School of Medicine

(b) (6)

**From:** Adam, Stacey (FNIH) [T] < (b) (6)>

**Sent:** Thursday, May 21, 2020 8:00 PM

**To:** Judy Currier < (b) (6)> Eric Hughes < (b) (6)> LaVange, Lisa M



<lisa. (b) (6) Sandeep Menon < (b) (6) Proschan, Michael (NIH/NIAID) [E]  
 < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Price, Dionne (FDA/CDER)  
 < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) Farley, John (FDA/CDER)  
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 < (b) (6) Fischer, William A. II < (b) (6) Eron, Joseph J Jr  
 < (b) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) Roa, Jhoanna (b) (6)  
 (b) (6) Kim, Peter (NIH/NIAID) [E] < (b) (6) Jonathan Li < (b) (6)  
 Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) Kozak, Marina (OS/ASPR/BARDA)  
 < (b) (6)  
 Cc: DeMarcus, Forrest < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan  
 < (b) (6) Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)  
 Jhoanna Roa < (b) (6) Eron, Joseph J Jr < (b) (6) Smith, David  
 < (b) (6) Paul Klekotka < (b) (6) Ajay Nirula < (b) (6) Elsaid,  
 Olivia < (b) (6) Robert Jan Benshop < (b) (6) Lei Shen < (b) (6)  
 Chen, Helen Q. < (b) (6)

**Subject:** Notes from the ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Dear ACTIV TX-Clinical mAb Outpatient WT,

Please find the notes from last night's writing team meeting for the group's reference. Please note the action items for follow up and the bolded text actions and decisions.

In addition, as requested, I am circulated the document of Statistical Considerations that Mike Proschan put together for ACTIV-1, the large Phase 3.

Thanks,  
Stacey

Stacey J. Adam, PhD  
 Director, Cancer  
 Research Partnerships  
 Foundation for the National Institutes of Health  
 Direct: (b) (6) ; Mobile: (b) (6)  
 fnih.org  
 11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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**Sent:** 8/14/2020 5:23:09 PM  
**To:** Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]  
**Subject:** RE: ACTIV website updates per EC slides/meeting today

Hi Lauren,

I think the response you've provided is appropriate. We can follow up with Emma and Renate today to let them know we understand the draft revisions for the webpages are in the hands of FNIH, David for review but we wanted to share that the executive committee met today and they are aware that the Clinical Capacity WG and Vaccine WG have completed their charge and ceased activity as of July 31, although the vaccines WG continues to meet on an ad hoc basis due to the ongoing vaccine trials.

We could say, we've included these details in the drafts however it was brought to our attention that this should be updated on the website.

Could you send this note in case there is follow-up while I am away next week?

**From:** Brodd, Lauren (NIH/OD) [E] <[REDACTED]> (b) (6)  
**Sent:** Friday, August 14, 2020 12:38 PM  
**To:** Parker, Ashley (NIH/OD) [E] <[REDACTED]> (b) (6)  
**Subject:** FW: ACTIV website updates per EC slides/meeting today

FYI below. Ellen raised the need to revise the website since two of the WG aren't meeting anymore. I told her we are working on revisions.

I'm guessing it is fine to wait to address this until all the changes are ready (so it doesn't have to be updated twice) but let me know if you think otherwise.

Thanks!  
Lauren

**From:** Brodd, Lauren (NIH/OD) [E]  
**Sent:** Friday, August 14, 2020 12:35 PM  
**To:** Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> (b) (6)  
**Subject:** RE: ACTIV website updates per EC slides/meeting today

Hi Ellen,

Thanks for flagging. Ashley and I have been working with Renate and her team to revise the website to provide more detailed information about each of the working groups. In the updated version, we include language about the clinical trial capacity group being finished as of 7/31 and the vaccines group now only meeting on an ad hoc basis. Not sure the exact timeline (FNIH is currently reviewing the drafts) but those groups will be addressed when the updated version goes live.

Thanks,  
Lauren

**From:** Gadbois, Ellen (NIH/OD) [E] <[REDACTED]> (b) (6)  
**Sent:** Friday, August 14, 2020 12:18 PM

**To:** Brodd, Lauren (NIH/OD) [E] <(b) (6)>  
**Subject:** ACTIV website updates per EC slides/meeting today  
**Importance:** High

You may want to revise how the working groups are listed on the website since clinical trials capacity is done, and vaccine is suspended (may be reconvened if needed)—see slides.

**From:** Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]

**Sent:** Thursday, August 13, 2020 10:20 PM

**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>; Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>;  
Dolsten, Mikael <(b) (6)>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>; Gibbons, Gary  
(NIH/NHLBI) [E] <(b) (6)>; Marks, Peter (FDA/CBER) <(b) (6)>; Pao, William  
<(b) (6)>; Plump, Andrew <(b) (6)>; Stoffels, Paul <(b) (6)>;  
Woodcock, Janet (FDA/CDER) <(b) (6)>; Colvis, Christine (NIH/NCATS) [E]  
<(b) (6)>; Desrosiers, Betsy <(b) (6)>; Eric Hughes  
<(b) (6)>; Jansen, Kathrin <(b) (6)>; Kurilla, Michael (NIH/NCATS) [E]  
<(b) (6)>; Lowy, Douglas (NCI) <(b) (6)>; Read, Sarah (NIH/NIAID) [E] <(b) (6)>;  
Young, John <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>  
**Cc:** Anderson, James (NIH/OD) [E] <(b) (6)>; Austin, Christopher (NIH/NCATS) [E]  
<(b) (6)>; Burklow, John (NIH/OD) [E] <(b) (6)>; Castillejos, Carlos <(b) (6)>;  
Culp, Michelle (NIH/OD) [E] <(b) (6)>; FNIH Central Account <(b) (6)>; Freire, Maria  
(FNIH) [T] <(b) (6)>; Gadbois, Ellen (NIH/OD) [E] <(b) (6)>; Hallett, Adrienne (NIH/OD) [E]  
<(b) (6)>; Lane, Cliff (NIH/NIAID) [E] <(b) (6)>; Myles, Renate (NIH/OD) [E]  
<(b) (6)>; Parker, Ashley (NIH/OD) [E] <(b) (6)>; Tabak, Lawrence (NIH/OD) [E]  
<(b) (6)>; Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>; Melencio, Cheryl (FNIH) [T]  
<(b) (6)>; Adam, Stacey (FNIH) [T] <(b) (6)>; Alvarez, Rosa <(b) (6)>;  
Anderson, Margaret <(b) (6)>; Chen, Helen <(b) (6)>; Elsaid, Olivia  
<(b) (6)>; Gonzalez, Nina <(b) (6)>; Hawk, Harrison <(b) (6)>;  
Menetski, Joseph (FNIH) [T] <(b) (6)>; Santos, Michael (FNIH) [T] <(b) (6)>; Stratton, Benjamin  
<(b) (6)>; Tolman, Brett <(b) (6)>; Tountas, Karen (FNIH) [T] <(b) (6)>;  
Wachtel, Jonathan <(b) (6)>

**Subject:** Materials for August 14 ACTIV Executive Committee Teleconference  
**Importance:** High

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from **12:00 – 1:00 PM Eastern U.S. time** tomorrow, Friday, August 14. I have also attached notes from our July 29 Leadership Team meeting as well as our last EC meeting on July 15. As you know we will be hearing from two Working Groups instead of four, **so the co-chairs have decided to make this call as well as future EC and LT calls going forward 60 minutes in length instead of 90 minutes.**

The Zoom information is:

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Please let Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health

(b) (6)

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(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) (b) (6) Puntunieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-puntuniera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)

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CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)

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 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) Diamond, Michael  
 [ (b) (6) Rose Li [ (b) (6) Dana Carluccio  
 [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange  
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[ (b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D (b) (6) ; Dave Frankowski [ (b) (6) Baric, Toni C [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]; Stratton, Benjamin [ (b) (6) Hawk, Harrison [ (b) (6) Mason, Stephen [ (b) (6) (b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

**Start:** 8/26/2020 2:00:00 PM

**End:** 8/26/2020 3:00:00 PM

**Recurrence:** (none)



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(b) (6) Greg Glenn [ (b) (6) (b) (6) Haynes,  
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Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda];  
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 USARMY MEDCOM WRAIR (USA) [ (b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD)  
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 [ (b) (6) Jacqueline Miller [ (b) (6) Kayvon Modjarrad  
 [ (b) (6)

**Subject:** Action: Review Vaccine-associated Enhanced Disease Manuscript  
**Attachments:** COVID - 19 Vaccine Development - VAED DRAFT 7.20.2020.docx

Dear Vaccines Working Group and Sub-Group Members,

Thanks to everyone who provided input on the previous version of the vaccine-associated enhanced disease manuscript that we shared. The authors have incorporated your feedback and made additional improvements. We are nearing submission to Science Translational Medicine, which has indicated interest.

Because the article is a product of the Working Group, we would appreciate your final review. **Could you kindly take a look at the manuscript and provide any feedback or comments you may have by Thursday, July 22 at 8 PM ET?**

Thank you for your help and we are excited to be nearing submission!

Sincerely,

Brett & Mike

This message (including any attachments) contains confidential information intended for a specific individual and purpose, and is protected by law. If you are not the intended recipient, you should delete this message and any disclosure, copying, or distribution of this message, or the taking of any action based on it, by you is strictly prohibited.

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**CC:** Mary Biggs [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6) Wachtel, Jonathan [ (b) (6) Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b224466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [ (b) (6) Wholley, David (FNIH) [T] [ (b) (6) Melencio, Cheryl (FNIH) [T] [ (b) (6) Wung, Peter /US [ (b) (6)  
**Subject:** ACTIV TX-Clinical Master Protocol Subgroup Meeting #9  
**Attachments:** ACTIV Therapeutics-Clinical\_MP Subgroup\_27Apr2020 Meeting Guide.pdf  
**Location:** <https://fnih.zoom.us> (b) (6)  
**Start:** 4/27/2020 6:00:00 PM  
**End:** 4/27/2020 7:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael  
**Optional Attendees:** Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the slides for today's discussion with updates from our statistical meeting over the weekend. We look forward to discussing this and a few other items with the group at today's meeting.

Thanks,  
Stacey

Join Zoom Meeting  
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US

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Find your local number: <https://fnih.zoom.us> (b) (6)

**From:** Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
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(b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];  
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
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ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; (b) (6)  
Alvarez, Rosa Maria [ (b) (6)  
**CC:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [ (b) (6) Tolman, Brett [ (b) (6) Wachtel, Jonathan [ (b) (6) ]; Prabhavathi Fernandes [ (b) (6) Diamond, Michael [ (b) (6) Rose Li [ (b) (6) Dana Carluccio [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]  
**Subject:** RE: COVID Preclinical Working group Meeting #2  
**Attachments:** PRECLINICAL Working Group FNIH\_Meeting 2\_0417\_vF4.pdf; 20200416\_PRECLINICAL Working Group\_Animal Models\_Actions and observations\_d3 docx; Inventory Template columns for WG review\_4 16 2020.xlsx; In vitro Subteam notes and actions 4 16 d4 docx



Hi all,

Please find attached a few materials for our discussion today:

1. Slides for our discussion today
2. Notes from the Animal Model Subgroup
3. Notes from the In Vitro Assay Subgroup
4. Framework for the preclinical data inventory (including data fields for the Preclinical compound list, Animal Model list, In vitro Assay List and BSL 3/4 Facilities List)

Please let us know if you have any modifications to the data fields to be included in the inventory

For logistic purposes, if you plan to call into the meeting with phone only, could you please send me your telephone number prior to the meeting. Having you number will allow me to keep track of who is attending the meetings.

Looking forward to our discussion at 11am ET.

Sincerely,

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] <(b) (6)>

Sent: Sunday, April 12, 2020 12:50 PM

To: Menetski, Joseph (FNIH) [T]:

(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) Baric, Ralph; Ottinger, Elizabeth  
(NIH/NCATS [E] Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon  
(FDA/CDER): (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD)  
[E]; (b) (6) Adams, Peter (OS/ASPR/BARDA), Jonson, Samantha (NIH/NCATS) [E]  
Cc: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E];  
Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael  
(NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos,  
Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim,  
Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana  
Carluccio; Lagos, Enrique (NIH/NCATS) [E]  
Subject: COVID Preclinical Working group Meeting #2  
When: Friday, April 17, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).  
Where: <https://zoom.us/j/98359338> (b) (6)

Saving time on the calendar.

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**Sent:** 2/17/2021 1:06:01 PM  
**Subject:** FW: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, February 17, 2021  
**Attachments:** 02.17.21 ACTIV EC and Leadership Team Meeting 20210216\_vF.pdf; 02.17.21 ACTIV EC and Leadership Team Meeting\_APPENDIX 20210216\_vF.pdf; 2021-01-14 ACTIV Leadership Team and Executive Committee Meeting\_Summary vF.pdf

**From:** Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, February 16, 2021 7:03 PM  
**To:** Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane  
<(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco  
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<(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>  
Victoria Davey <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael  
<(b) (6)> Embry, Alan (NIH/NIAID) [E] <(b) (6)> Erbeling, Emily (NIH/NIAID) [E]  
<(b) (6)> Erck, Stan <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>  
Freire, Maria (FNIH) [T] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Gibbons, Gary  
(NIH/NHLBI) [E] <(b) (6)> Hudson, Thomas <(b) (6)> James, Stephanie (FNIH) [T]  
<(b) (6)> Johnson, Robert (OS/ASPR/BARDA) <(b) (6)> Kramer, Lynn  
<(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Lepore, John <(b) (6)>  
Marks, Peter (FDA/CBER) <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker,  
David <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Messonnier, Nancy  
(CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh <(b) (6)> Pangalos, Mene  
<(b) (6)> Pao, William <(b) (6)> Parker, Ashley (NIH/OD) [E]  
<(b) (6)> Paul, Steve <(b) (6)> Perlmutter, Roger <(b) (6)>  
Plenge, Robert <(b) (6)> Plump, Andy <(b) (6)> Rachel Ramoni  
<(b) (6)> Reed, John <(b) (6)> Reese, David <(b) (6)> Rouse, Doris  
<(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Skovronsky, Daniel <(b) (6)>  
Stein, Peter (FDA/CDER) <(b) (6)> Stoffels, Paul <(b) (6)> Tabak, Lawrence (NIH/OD)  
[E] <(b) (6)> Talley, Michael <(b) (6)> Tsai, John <(b) (6)>  
Vessey, Rupert <(b) (6)> Virgin, Skip <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>  
Woodcock, Janet (FDA/OC) <(b) (6)> Young, John <(b) (6)> Colvis,  
Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy <(b) (6)> Eric  
Hughes <(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]  
<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>  
Young, John <(b) (6)>  
**Cc:** Anderson, James (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)>  
Carluccio, Dana <(b) (6)> Castillejos, Carlos <(b) (6)> Culp, Michelle  
(NIH/OD) [E] <(b) (6)> FNIH Central Account <(b) (6)> Gadbois, Ellen (NIH/OD) [E]  
<(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Lumsden, Joanne (NIH/NCATS) [C]  
<(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E]  
<(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Margaret Anderson  
<(b) (6)> Appell, Evan <(b) (6)> Chen, Helen <(b) (6)>  
Connelly, Sarah <(b) (6)> Dally, Nicole <(b) (6)> Gonzalez, Nina  
<(b) (6)> Hawk, Harrison <(b) (6)> Mendelson, Jesse <(b) (6)>  
Menetski, Joseph (FNIH) [T] <(b) (6)> Nasr, Hana <(b) (6)> Santos, Michael (FNIH) [T]  
<(b) (6)> Sorosa, Alex <(b) (6)> Stratton, Benjamin <(b) (6)> Tolman,  
Brett <(b) (6)> Wachtel, Jonathan <(b) (6)> Wholley, David (FNIH) [T]  
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<(b) (6)> Meltzer, Abbey (FNIH) [T] <(b) (6)> Myles, Renate (NIH/OD) [E]

< (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6)

**Subject:** ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, February 17, 2021

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, February 17, from 11:30 a.m. to 1:00 p.m. Eastern U.S. Time.** The minutes from the January 14 Executive Committee/Leadership Team call are also attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health

(b) (6)

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*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*

**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

**Sent:** 5/19/2020 2:32:19 AM

**To:** Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [ (b) (6) ]; LaVange, Lisa M [ (b) (6) ]; Sandeep Menon [ (b) (6) ]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [ (b) (6) ]; Eron, Joe [ (b) (6) ]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]

**CC:** Demarcus [ (b) (6) ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) ]; Elizabeth Kim [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [ (b) (6) ]; Eron, Joseph J Jr [ (b) (6) ]; Smith, David [ (b) (6) ]; Paul Klekotka [ (b) (6) ]; Ajay Nirula [ (b) (6) ]

**Subject:** HOLD for Potential: ACTIV TX-Clinical Neutralizing mAb Outpat ent MP Writing Team Meeting

**Location:** <https://fnih.zoom.us/j> (b) (6)

**Start:** 5/19/2020 8:00:00 PM

**End:** 5/19/2020 9:30:00 PM

**Show Time As:** Tentative

**Required Attendees:** Judy Currier; Eric Hughes, Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; (b) (6); (b) (6); (b) (6); (b) (6); Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6); Kim, Peter (NIH/NIAID) [E]

**Optional Attendees:** Demarcus, Tountas, Karen (FNIH) [T]; Wachtel, Jonathan, Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula

Dear ACTIV-2 Writing Team,

Please save this time if you can for our next writing team meeting. While I am still waiting on a few critical confirmations since majority can make it, I want to go ahead and block it off.

An agenda will be send once we have the necessary participants confirmed.

Thanks.

Stacey

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**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-MELENCIOC]

**Sent:** 7/21/2020 7:19:32 PM

**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Bancel, Stephane [ (b) (6) Carter, Kara [ (b) (6) Cavaleri, Marco [ (b) (6) Cihlar, Tomas [ (b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [ (b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Do sten, Mikael [ (b) (6) Erbeling, Emily (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Erck, Stan [ (b) (6) Fauci, Anthony (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [ (b) (6) Lane, Cliff (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [ (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, H lary (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [ (b) (6) ]; Meeker, David [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aebc9a0d9b96c-NAR5]; Pandya, Hitesh [ (b) (6) Pao, William [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Perlmutter, Roger [ (b) (6) Plenge, Robert [ (b) (6) Plump, Andy [ (b) (6) Rachel Ramon [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido [ (b) (6) Reed, John [ (b) (6) Reese, David [ (b) (6) Rouse, Doris [ (b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [ (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Tal ey, Michael [ (b) (6) Tsai, John [ (b) (6) Vessey, Rupert [ (b) (6) ]; Virgin, Skip [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative

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[ (b) (6) Anderson, Margaret [ (b) (6) Chen, Helen  
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[ (b) (6) FNIH Central Account [ (b) (6) Hallett, Adrienne (NIH/OD) [E]  
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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[C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Togashi, Meko (NIH/NCI)  
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashm]; Underwood, Nancy  
[ (b) (6) Zottoli, Jessica [ (b) (6) Austin, Sarah (NIH/NIAID) [E]  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly  
(NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia  
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne  
(NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan  
[ (b) (6) Giorgi, Sara [ (b) (6) Hoban, Michelle [ (b) (6)  
Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group



(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; IBERDEMA, VAIDE  
[ (b) (6) Lever, Susan (b) (6) McManus, Ayanna (NIH/OD) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth  
 (b) (6) ; Peralá, Mie [ (b) (6) Protasiewicz, Ann  
 [ (b) (6) Riccobene, Kim [ (b) (6) Riggín, Mary [ (b) (6)  
 Ripley, Nadege [ (b) (6) Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange  
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana];  
 Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen  
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; David Meeker  
 [ (b) (6) Dana Carluccio [ (b) (6) Hawk, Harrison  
 [ (b) (6) Lucas Smalldon [ (b) (6) Hamilton, Nancy  
 [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Vessey, Rupert  
 [ (b) (6) ]

**Subject:** ACTIV Leadership Team Call #7  
**Attachments:** Materials for August 26 ACTIV Partnership Leadership Team Teleconference  
**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 8/26/2020 7:00:00 PM  
**End:** 8/26/2020 8:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauc, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; G bbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ash ey (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Ras, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy, Hughes, Eric; Jansen, Kathrin, Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Villafana, Tonya; Brian Rosen

**Optional Attendees:** Adam, Stacey (FNIH) [T]; Alvarez, Rosa, Anderson, Margaret; Chen, Helen; Elsaid, Ol via; Gonzalez, Nina; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan, Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy, Zotto i, Jessica, Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; IBERDEMA, VAIDE; lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Peralá, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggín, Mary; Ripley, Nadege; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; David Meeker; Dana Carluccio; Hawk, Harrison; Vessey, Rupert; Lucas Smalldon; Hamilton, Nancy; Lowy, Douglas (NIH/NCI) [E]

Shortening calls to one hour in length

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

**Sent:** 4/21/2020 1:52:51 AM

**To:** Eric Hughes [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [ (b) (6) ]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [ (b) (6) ]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [ (b) (6) ]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [ (b) (6) ]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [ (b) (6) ]

**CC:** Elizabeth Kim [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski]; Alvarez, Rosa Maria [ (b) (6) ]; Salathin, Carla [ (b) (6) ]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [ (b) (6) ]

**Subject:** ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting

**Attachments:** ACTIV Therapeutics Clinical Agent Prioritization Sub-Group Meeting Agenda 04192020.pdf; ACTIV Therapeutics-Clinical AP Subgroup Meeting 2 21Apr2020 Meeting Guide.pdf; C-19 pipeline by BIO IA 2020-04-19.pdf; 2. Wave 2 Summary\_v5[1].xlsx; ACTIVPrioritizationCriteria-v3.xlsx

**Location:** <https://fnih.zoom>. (b) (6)

**Start:** 4/21/2020 6:00:00 PM

**End:** 4/21/2020 7:00:00 PM

**Show Time As:** Tentative

**Required Attendees:** Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael

**Optional Attendees:** Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for tomorrow's call.

1. Agenda
2. Slides for presentation – You will notice that these contain not only our suggested Agent Prioritization Process and Criteria, but also contain the already prioritized list of agents from other groups that have been kind enough to share with us.
3. Excel spreadsheet of the list the ACCORD team started with for prioritization
4. PDF of assessment that BIO did of their members pipelines for antiviral candidates and list that they came up with for potential use.
5. Updated Prioritization Criteria for the Group's Review and comment. (Excel Spreadsheet)

We look forward to seeing many of you for this discussion.

Thanks,

Stacey

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**From:** Michael Hughes [ (b) (6) ]  
**Sent:** 5/21/2020 5:48:46 PM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; LaVange, Lisa M [ (b) (6) ]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Eron, Joseph J Jr [ (b) (6) ]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [ (b) (6) ]; Sandeep Menon [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [ (b) (6) ]; smith.davey [ (b) (6) ]; chew.kara [ (b) (6) ]; Wohl, David A [ (b) (6) ]; Fischer, William A. II [ (b) (6) ]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; li.jonathan [ (b) (6) ]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]  
**CC:** DeMarcus, Forrest [ (b) (6) ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) ]; Elizabeth Kim [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; roa.jhoanna [ (b) (6) ]; Smith, David [ (b) (6) ]; Paul Klekotka [ (b) (6) ]; Ajay Nirula [ (b) (6) ]; Elsaid, Olivia [ (b) (6) ]; Robert Jan Benschoep [ (b) (6) ]; Lei Shen [ (b) (6) ]  
**Subject:** Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Hi Stacey:

Tomorrow, I can make the following times:

8-9:30 EDT

10:30-2 EDT

4:30 onwards EDT

Michael

---

**From:** Adam, Stacey (FNIH) [T] < (b) (6) >  
**Sent:** Thursday, May 21, 2020 1:41 PM  
**To:** LaVange, Lisa M; Michael Hughes; Proschan, Michael (NIH/NIAID) [E]; Eron, Joseph J Jr; currier,udith; Eric Hughes;

APAR0000005313-2517113

Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey; (b) (6) chew.kara; Wohl, David A; Fischer, William A. II; avan.arzhang; Roa, Jhoanna; (b) (6) kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)

**Cc:** DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen

**Subject:** RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Hi Lisa,

You are correct. I did have on my to do list for today to get together a meeting of the statistical team for either tonight, tomorrow, or Saturday, according to my notes.

I was going to send a note to the stats group for their availability, but if you all wanted to suggest times for tomorrow that you are available on this thread, I will work to get a meeting scheduled and an invite out.

Thanks,  
STacey

**Stacey J. Adam, PhD**

Director, Cancer

Research Partnerships

Direct: (b) (6) Mobile: (b) (6)

**From:** LaVange, Lisa M <(b) (6)>

**Sent:** Thursday, May 21, 2020 1:34 PM

**Subject:** RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks, Michael I believe it is premature to submit the protocol to your internal review committee. My take-away from yesterday's meeting was that the next step would be for the subgroup of statisticians to meet to discuss the simulations required for the revised trial design. The proposed revisions to the design are needed, in my opinion, to give us the type of flexible, fast-moving master protocol we need to screen a large amount of monoclonal antibodies. But we need to work out some of the design details, so let's have that next meeting as planned. Hoping we can schedule it for some time tomorrow and will work with Stacey to find a time.

Lisa

**From:** Michael Hughes [mailto:(b) (6)]

**Sent:** Thursday, May 21, 2020 11:03 AM

**Subject:** Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Hi All:

The ACTG team was hoping to submit the A5401 protocol tomorrow to the NIAID Clinical Science Review Committee for their review. The protocol design uses standard (widely-used) statistical methods for interim and final analyses but we received the feedback (attached) from ACTIV about moving to fully use Bayesian methods, so wanted to respond and get thoughts back as this is a substantial change --- and would mean that we would not be able to send for CSRC tomorrow.

I have particular concerns about the need to use the Bayesian paradigm, particularly for Phase III. For a given agent, the Phase 3 study is a fairly simple study involving evaluations for safety, clinical symptoms, and the primary outcome measure of hospitalization/death. We proposed to use standard group sequential monitoring methods which are flexible (using the Lan-DeMets approach for flexible timing of Interim analyses with an O'Brien and Fleming type stopping guideline). I think the seamless phase II to phase 3 aspect of the design can be incorporated into this flexible approach by just considering the "look" at the data at the end of phase II as one "look" at the phase 3 primary outcome. This provides protection for the Type I error rate for each specific agent. We can overlay a the possibility of a simple futility rule, eg at  $\geq 50\%$  enrollment, to allow stopping for lack of effect (can be justified using a Type II spending boundary, conditional power, or even a Bayesian type rule).

I think this is all quite straightforward. I worry that putting the Phase 3 trial into the Bayesian paradigm gains very little but adds complexity in terms of having to confirm that any Bayesian decision rule does protect Type I error rate for regulatory purposes, and in terms of explaining to many different companies and ultimately to a broad audience. In addition, if the study does go global, it increases the complexity of explaining to IRBs and other review groups.

I would prefer to leave Phase 3 using standard (widely used) statistical methods. I would also favor using standard methods for analysis of Phase 2 data but do agree that Bayesian analyses might also be used for the main efficacy outcome measures to provide an additional perspective in decision-making --- though the main graduation rules (eg observing an absolute 20% reduction in % positive for SARS-CoV-2 at an measurement time, and/or a 20% reduction in mean symptom duration) are straightforward and well-powered.

I would welcome feedback.

Many thanks,  
Michael

---

**From:** Proschan, Michael (NIH/NIAID) [E] < > (b) (6)

**Sent:** Thursday, May 21, 2020 8:52 AM

**To:** LaVange, Lisa M; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey, Michael Hughes; (b) (6) chew.kara; Wohl, David A, Fischer, William A. II; javan.arzhang; Roa, Jhoanna;

(b) (6) kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)

**Cc:** DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen

**Subject:** RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

I think the question is whether we could stop early for efficacy as well as stopping early for futility. That could certainly be incorporated if you think there is a realistic possibility of crossing an efficacy boundary after only 50 people. At the halfway point, the O'Brien-Fleming-like spending function boundary for the z-score is close to 3, so you would have to see a very large z-score to stop that early for efficacy.

Mike.



**From:** LaVange, Lisa M <(b) (6)>  
**Sent:** Thursday, May 21, 2020 7:53 AM  
**To:** Eron, Joseph J Jr <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Judy Currier  
 <(b) (6)> Eric Hughes <(b) (6)> Sandeep Menon  
 <(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah  
 (NIH/NIAID) [E] <(b) (6)> Price, Dionne (FDA/CDER) <(b) (6)> Rubin, Daniel B.  
 (FDA/CDER) <(b) (6)> Farley, John (FDA/CDER) <(b) (6)> Karen Lynn Price  
 (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)  
 (b) (6) (b) (6) Wohl, David A (b) (6) (b) (6) Fischer, William A. II  
 (b) (6) (b) (6) Javan, Arzhang (NIH/NIAID) [E] <(b) (6)> Roa, Jhoanna (b) (6)  
 (b) (6) Kim, Peter (NIH/NIAID) [E] <(b) (6)> Jonathan Li <(b) (6)>  
 Marks, Gilbert (OS/ASPR/BARDA) (CTR) <(b) (6)> Kozak, Marina (OS/ASPR/BARDA)  
 <(b) (6)>  
**Cc:** DeMarcus, Forrest <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan  
 <(b) (6)> Elizabeth Kim <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>  
 Jhoanna Roa <(b) (6)> Smith, David <(b) (6)> Paul Klekotka  
 (b) (6) (b) (6) Ajay Nirula (b) (6) Elsaid, Olivia <(b) (6)> Robert Jan  
 Benschop (b) (6) (b) (6) Lei Shen (b) (6) (b) (6)  
**Subject:** RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

This seems reasonable to me. We can define any basis that we think will be important for dropping dose arms or entire agents, having little to go on at this point in terms of what best predicts hospitalizations.  
 Lisa

**From:** Eron, Joseph J Jr  
**Sent:** Wednesday, May 20, 2020 6:23 PM  
**To:** Adam, Stacey (FNIH) [T] <(b) (6)> Judy Currier <(b) (6)> Eric Hughes  
 <(b) (6)> LaVange, Lisa M <(b) (6)> Sandeep Menon  
 <(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah  
 (NIH/NIAID) [E] <(b) (6)> Price, Dionne (FDA/CDER) <(b) (6)> Rubin, Daniel B.  
 (FDA/CDER) <(b) (6)> Farley, John (FDA/CDER) <(b) (6)> Karen Lynn Price  
 (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)  
 (b) (6) (b) (6) Wohl, David A (b) (6) (b) (6) Fischer, William A. II  
 (b) (6) (b) (6) Javan, Arzhang (NIH/NIAID) [E] <(b) (6)> Roa, Jhoanna (b) (6)  
 ; (b) (6) Kim, Peter (NIH/NIAID) [E] <(b) (6)> Jonathan Li <(b) (6)>  
 Marks, Gilbert (OS/ASPR/BARDA) (CTR) <(b) (6)> Kozak, Marina (OS/ASPR/BARDA)  
 <(b) (6)>  
**Cc:** DeMarcus, Forrest <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan  
 <(b) (6)> Elizabeth Kim <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>  
 Jhoanna Roa <(b) (6)> Smith, David <(b) (6)> Paul Klekotka  
 (b) (6) Ajay Nirula (b) (6) Elsaid, Olivia <(b) (6)> Robert Jan  
 Benschop (b) (6) Lei Shen (b) (6)  
**Subject:** RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Here is my question for the group – especially Michael, John and Lisa  
 My question is whether there could be an interim “activity” analysis similar to the futility analysis listed below – the reason I ask is we have very little longitudinal data on the quantitative viral shedding and it is possible that this endpoint would have substantial power such that 50 patients per arm could provide an antiviral answer.

- If the Phase 2 portion of the Clinical mAb protocol is used for dose finding, this may be challenging with respect to size of the trial (number of treatment arms needed and available sample size per treatment arm). In addition, it may be appropriate to establish an interim futility analysis based on change in quantitative viral shedding to allow for

discontinuation of a dose after e.g. 50 rather than 110 patients, or to allow early discontinuation of high doses due to safety findings.

Joe Eron MD  
Professor of Medicine  
University of North Carolina at Chapel Hill  
School of Medicine  
(b) (6)

**From:** Adam, Stacey (FNIH) [T] < (b) (6) >

**Sent:** Wednesday, May 20, 2020 5:42 PM

**To:** Judy Currier < (b) (6) > Eric Hughes < (b) (6) > LaVange, Lisa M  
< (b) (6) > Sandeep Menon < (b) (6) > Proschan, Michael (NIH/NIAID) [E]  
< (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Price, Dionne (FDA/CDER)  
< (b) (6) > Rubin, Daniel B. (FDA/CDER) (b) (6) (b) (6) Farley, John (FDA/CDER)  
< (b) (6) > Karen Lynn Price (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) Wohl, David A  
(b) (6) (b) (6) Fischer, William A. II (b) (6) Eron, Joseph J Jr  
(b) (6) (b) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) > Roa, Jhoanna (b) (6)  
(b) (6) Kim, Peter (NIH/NIAID) [E] < (b) (6) > Jonathan Li < (b) (6) >  
Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) > Kozak, Marina (OS/ASPR/BARDA)  
< (b) (6) >  
**Cc:** DeMarcus, Forrest < (b) (6) > Tountas, Karen (FNIH) [T] < (b) (6) > Wachtel, Jonathan  
< (b) (6) > Elizabeth Kim < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >  
Jhoanna Roa < (b) (6) > Eron, Joseph J Jr (b) (6) Smith, David  
< (b) (6) > Paul Klekotka (b) (6) Ajay Nirula (b) (6) Elsaid,  
Olivia < (b) (6) > Robert Jan Benschop (b) (6) : Lei Shen (b) (6)  
**Subject:** RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Dear mAb Outpatient WT,

The FDA team that has been working with ACTIV and sitting in on our writing team meetings for this protocol would like to offer the attached thoughts for the group's consideration on tonight's call.

Also, attaching again the updated synopsis that was discussed with the mAb Steering Committee earlier today.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Direct: (b) (6) | Mobile: (b) (6)

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US (San Jose)

US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

**From:** Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]  
**Sent:** 4/15/2020 6:08:29 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]  
**Subject:** RE: List -- just copy and paste in bcc. lists of April 3 plus working groups  
**Attachments:** Master list for ACTIV 041520.xlsx

Francis -- the following emails were missing from the list that went out, please see 8 emails listed below

Cheryl -- attached is a revised master list (114 contacts) with names and emails which includes everyone.

Disbrow, Gary (OS/ASPR/BARDA) < (b) (6)>  
Kim, Elizabeth < (b) (6)>  
Marston, Hilary (NIH/NIAID) [E] < (b) (6)>  
Paul, Steve < (b) (6)>  
Payne, David < (b) (6)>  
Plump, Andy < (b) (6)>  
Santos, Nancy < (b) (6)> ;  
Shen, Yuan Li (FDA/CDER) < (b) (6)>

Thanks,  
Ashley

**From:** Collins, Francis (NIH/OD) [E] < (b) (6)>  
**Sent:** Wednesday, April 15, 2020 11:39 AM  
**To:** Melencio, Cheryl (FNIH) [T] < (b) (6)> Parker, Ashley (NIH/OD) [E] < (b) (6)>  
**Subject:** RE: List -- just copy and paste in bcc. lists of April 3 plus working groups

I already sent the other list, given the time sensitivity. What has been added here that wasn't in the other one?

**From:** Melencio, Cheryl (FNIH) [T] < (b) (6)> < (b) (6)>  
**Sent:** Wednesday, April 15, 2020 11:19 AM  
**To:** Parker, Ashley (NIH/OD) [E] < (b) (6)> Collins, Francis (NIH/OD) [E] < (b) (6)>  
**Subject:** List -- just copy and paste in bcc. lists of April 3 plus working groups

Austin, Christopher (NIH/NCATS) [E] < (b) (6)> Bright, Rick < (b) (6)> Collins, Francis (NIH/OD) [E] < (b) (6)> >; Corey, Larry < (b) (6)> ; Disbrow, Gary (OS/ASPR/BARDA) < (b) (6)> >; Dolsten, Mikael < (b) (6)> >; Erbeling, Emily (NIH/NIAID) [E] < (b) (6)> >; Fauci, Anthony (NIH/NIAID) [E] < (b) (6)> >; Frankowski, David < (b) (6)> >; Hudson, Thomas < (b) (6)> >; James, Stephanie (FNIH) [T] < (b) (6)> >; Klock, Kevin (FNIH) [T] < (b) (6)> Lane, Cliff (NIH/NIAID) [E] < (b) (6)> >; Marks, Peter (FDA/CBER) < (b) (6)> Marston, Hilary (NIH/NIAID) [E] < (b) (6)> >; Mascola, John < (b) (6)> >; Meeker, David < (b) (6)> Menetski, Joseph (FNIH) [T] < (b) (6)> >; Pangalos, Mene < (b) (6)> Pao, William < (b) (6)> >; Paul, Steve < (b) (6)> >; Perlmutter, Roger < (b) (6)> Plump, Andy < (b) (6)> >; Rasi, Guido < (b) (6)> >; Reed, John < (b) (6)> >; Rouse, < (b) (6)>

Doris (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) Skovronsky, Daniel  
 (b) (6) . Stein, Peter (FDA/CDER) (b) (6) >; Stoffels, Paul  
 (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Tsai, John  
 (b) (6) Vessey, Rupert < (b) (6) >; Virgin, Skip (b) (6) Wholley, David  
 (FNIH) [T] (b) (6) >; Woodcock, Janet (FDA/CDER) (b) (6) >; Young, John  
 < (b) (6) Adam, Stacey (FNIH) [T] (b) (6) >; Bascles, Lionel  
 (b) (6) Cohen, Myron < (b) (6) >; Corey, Larry (b) (6) ;  
 Desrosiers, Betsy (b) (6) Dickens, Jim (NIH/NCATS) [C] (b) (6) >;  
 Doroshov, James (NIH/NCI) [E] (b) (6) >; Goff, David (NIH/NHLBI) [E] < (b) (6) Heaton,  
 Penny < (b) (6) King, James (b) (6) >; Kurilla, Mike (b) (6) >; Nayak,  
 Seema (NIH/NIAID) [E] (b) (6) ; Parker, Ashley (NIH/OD) [E] < (b) (6) . Payton, Manzine  
 (b) (6) >; Resnansky, Laura (b) (6) >; Srinivasan, Badhri  
 (b) (6) ; Stein, Peter (FDA/CDER) (b) (6) : Tountas, Karen (FNIH) [T]  
 (b) (6) ; Vincent, Mike (b) (6) >; Wachtel, Jonathan (b) (6)  
 Woodcock, Janet (FDA/CDER) < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Bozzette,  
 Sam (NIH/NCATS) [E] < (b) (6) >; Buchman, Tim (OS/ASPR/BARDA) (CTR) (b) (6) >;  
 Butterson, Joan (b) (6) >; De Claro, R. Angelo (FDA/CDER) (b) (6)  
 Draghila-Akli, Ruxandra < (b) (6) . Elsner, Mark < (b) (6) Gottesdiener, Keith  
 (b) (6) >; Hughes, Eric (b) (6) : Judy Currier  
 < (b) (6) Kim, Elizabeth (b) (6) >; LaVange, Lisa (b) (6) >; Levy, Elliot  
 (b) (6) . Mellors, John < (b) (6) Menon, Sandeep < (b) (6) Parker,  
 Ashley (NIH/OD) [E] (b) (6) >; Patel, Naimish (b) (6) >; Peppercorn, Amanda  
 (b) (6) >; Poole, Mike (b) (6) >; Proschan, Michael  
 (b) (6) ; Read, Sarah (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) Shen,  
 Yuan Li (FDA/CDER) (b) (6) . Stein, Peter (FDA/CDER) (b) (6) ; Adams, Peter  
 (OS/ASPR/BARDA) (b) (6) >; Alvarez, Rosa (b) (6) >; Anderson, Annaliesa  
 < (b) (6) Baric, Ralph (b) (6) Carter, Kara (b) (6)  
 Colvis, Christine (b) (6) >; Deming, Damon (FDA/CDER) < (b) (6) Diamond,  
 Michael (b) (6) ; Duncan, Ken (b) (6) ; Fernandes, Prabhavathi  
 (b) (6) . Gatto, Greg (b) (6) Grobler, Jay (b) (6) >; Hewitt, Judith  
 (b) (6) ; Jonson, Samantha (NIH/NCATS) [E] < (b) (6) ; Lutz, Cat (b) (6)  
 Menetski, Joseph (FNIH) [T] < (b) (6) Nestle, Frank (b) (6) Ottinger, Liz  
 (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) Payne, David  
 < (b) (6) Rappaport, Jay (b) (6) >; Stegmeier, Frank <f> (b) (6)  
 Young, John < (b) (6) . Annunziato, Paula (b) (6) . Arvin, Ann  
 (b) (6) Buchbinder, Susan (b) (6) ; Corey, Larry (b) (6) >;  
 Davis, Mark < (b) (6) Emmini, Emilio < (b) (6) Hanon, Emmanuel  
 < (b) (6) Haynes, Barton < (b) (6) . Hotez, Peter < (b) (6) . Jansen,  
 Kathryn (b) (6) >; Lanzavecchia, Antonio < (b) (6) >; Lowy, Douglas (NIH/NCI) [E]  
 < (b) (6) Marks, Peter (FDA/CDER) < (b) (6) ; Mascola, John (NIH/VRC) [E]  
 (b) (6) ; Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6) ; Offit, Paul  
 (b) (6) Parker, Ashley (NIH/OD) [E] (b) (6) Santos, Nancy (b) (6) >;  
 Schuitemaker, Hanneke < (b) (6) Tartaglia, Jim < (b) (6) Tolman, Brett  
 (b) (6) (b) (6) (b) (6)

# **Cheryl Melencio**

Administrative Manager, Research Partnerships  
 Foundation for the National Institutes of Health  
 (b) (6)

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**From:** Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]  
**Sent:** 5/11/2020 4:47:38 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]  
**CC:** Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]  
**Subject:** RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Thanks so much, Cheryl!

**From:** Melencio, Cheryl (FNIH) [T] < (b) (6) >  
**Sent:** Monday, May 11, 2020 12:47 PM  
**To:** Parker, Ashley (NIH/OD) [E] < (b) (6) >; Wood, Gretchen (NIH/OD) [E] < (b) (6) >  
**Cc:** Hardesty, Rebecca (NIH/OD) [C] < (b) (6) >  
**Subject:** RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

I'll send her the invite and copy her assistant, Rebecca.

Cheryl Melencio  
Administrative Manager, Research Partnerships  
Foundation for the National Institutes of Health  
(b) (6)

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**From:** Parker, Ashley (NIH/OD) [E] < (b) (6) >  
**Sent:** Monday, May 11, 2020 12:46 PM  
**To:** Wood, Gretchen (NIH/OD) [E] < (b) (6) >; Melencio, Cheryl (FNIH) [T] < (b) (6) >  
**Cc:** Hardesty, Rebecca (NIH/OD) [C] < (b) (6) >  
**Subject:** RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Hi Gretchen and Cheryl,

Dr. Carrie Wolinetz would like to join this meeting. Cheryl – should I forward the invite or would you prefer to add on your end?

Thank you,  
Ashley



**From:** Wood, Gretchen (NIH/OD) [E] (b) (6) >  
**Sent:** Monday, May 11, 2020 9:23 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6) Fauci, Anthony (NIH/NIAID) [E] < (b) (6) >; Gibbons, Gary (NIH/NHLBI) [E] < (b) (6) > Stoffels, Paul < (b) (6) > Pao, William (b) (6) >; Dolsten, Mikael (b) (6) >; Colvis, Christine (NIH/NCATS) [E] (b) (6) >; Desrosiers, Betsy (b) (6) >; Hughes, Eric (b) (6) >; Jansen, Kathrin (b) (6) >; Kurilla, Michael (NIH/NCATS) [E] (b) (6) >; Lowy, Douglas (NCI) (b) (6) > Read, Sarah (NIH/NIAID) [E] (b) (6) > Young, John (b) (6) >  
**Cc:** Wholley, David (FNIH) [T] (b) (6) >; Menetski, Joseph (FNIH) [T] < (b) (6) > Adam, Stacey (FNIH) [T] (b) (6) >; Tountas, Karen (FNIH) [T] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) >; Freire, Maria (FNIH) [T] < (b) (6) > Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] < (b) (6) > Anderson, James (NIH/OD) [E] (b) (6) > Austin, Christopher (NIH/NCATS) [E] < (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6) >  
**Subject:** Re: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Good morning,

Please mark your calendars for Wednesday, May 13, from 8:00 AM-9:00 AM ET for this call. A calendar invitation will be shared with you soon.

With very best wishes,

Gretchen

**From:** Francis Collins < (b) (6) >  
**Date:** Saturday, May 9, 2020 at 1:07 PM  
**To:** Francis Collins (b) (6) >, Anthony Fauci (b) (6) >, "Gibbons, Gary (NIH/NHLBI) [E]" (b) (6) >, " (b) (6) >, Gretchen Wood < (b) (6) > "Pao, William" < (b) (6) > . " (b) (6) > "Colvis, Christine (NIH/NCATS) [E]" < (b) (6) > . "Desrosiers, Betsy" < (b) (6) > , "Hughes, Eric" (b) (6) > . "Jansen, Kathrin" (b) (6) > , "Kurilla, Michael (NIH/NCATS) [E]" < (b) (6) > "Lowy, Douglas (NCI)" (b) (6) > , "Read, Sarah (NIH/NIAID) [E]" < (b) (6) > "Young, John" (b) (6) >  
**Cc:** David Wholley (b) (6) >, "Menetski, Joseph (FNIH) [T]" (b) (6) >, "Adam, Stacey (FNIH) [T]" (b) (6) >, "Tountas, Karen (FNIH) [T]" < (b) (6) > "Santos, Michael (FNIH) [T]" (b) (6) >, Maria Freire (b) (6) >, "Tabak, Lawrence (NIH/OD) [E]" (b) (6) >, "Lane, Cliff (NIH/NIAID) [E]" < (b) (6) > Ashley Parker < (b) (6) > James Anderson (b) (6) >, "Austin, Christopher (NIH/NCATS) [E]" < (b) (6) >, "Melencio, Cheryl (FNIH) [T]" (b) (6) >, Gretchen Wood < (b) (6) >  
**Subject:** Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Dear ACTIV Executive Committee Members and Working Group Co-Chairs.

Although our next formal ACTIV EC meeting is not scheduled until May 20, I am aware of some concerns that are being voiced among our Working Group members. Some of those focus on the next steps for ACTIV, and especially about implementation of the plans these groups have been working so hard to put together. There are also concerns about

now we should best communicate across our partnership and coordinate with the many parallel (and in some cases conflicting) efforts that have emerged elsewhere—including among our own ACTIV members.

These are all very valid issues, and I believe they should be discussed by our dedicated team sooner rather than later. A meeting of the minds is particularly timely now, in the wake of a successful Leadership Team call on Wednesday and the establishment just this week of an Executive Committee to guide us moving forward. Therefore, I would like to make it a priority that the EC and the Working Group co-Chairs meet early next week to discuss and sync up on these important issues. Gretchen Wood on my staff will work with Cheryl Melencio at FNIH to reach out to you to get a suitable hourlong virtual conference set up—a morning meeting would make it easier to include Tony Fauci (because of White House duties in the afternoon) and Paul Stoffels (because of European time zones).

Thanks for all you are doing for the cause, and best regards,

Francis

**From:** Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]

**Sent:** 4/22/2020 6:42:29 PM

**To:** Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];  
 (b) (6) Lowy, Douglas (NIH/NCI) [E] [ (b) (6) ]; (b) (6)  
 Arvin, Ann [ (b) (6) Beth Bell [ (b) (6) [ (b) (6) (b) (6)  
 (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)  
 (b) (6) Haynes, Barton [ (b) (6) (b) (6) (b) (6)  
 Marks, Peter (FDA/CBER) [ (b) (6) ], Mascola, John (NIH/VRC) [E] [ (b) (6)  
 Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) Michael, Nelson L CIV USARMY MEDCOM WRAIR  
 (USA) [ (b) (6) Offit, Paul [ (b) (6) (b) (6) Seals, Jonathan  
 (OS/ASPR/BARDA) [ (b) (6) (b) (6) Tal Zaks [ (b) (6)  
**CC:** Kathleen Neuzil [ (b) (6) Merlin Robb [ (b) (6) Marovich, Mary (NIH/NIAID) [E]  
 [ (b) (6) ]; Cohen, Myron [ (b) (6) Tolman, Brett [ (b) (6)  
 (b) (6) Hopps, Markay [ (b) (6) Kozlowski, Mary (NIH/NCI) [C]  
 [ (b) (6) ]; Johnson, Maureen (NIH/NCI) [E] [ (b) (6) (b) (6)  
 (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]  
 [ (b) (6) Suhana, Tina (NIH/VRC) [E] [ (b) (6) (b) (6)  
 Isabel Ramsey [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange  
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];  
 Collins, Francis (NIH/OD) [E] [ (b) (6) .gov]; Wood, Gretchen (NIH/OD) [E] [ (b) (6) ]; Wholley,  
 David (FNIH) [T] [ (b) (6) Menetski, Joseph (FNIH) [T] [ (b) (6) Adam, Stacey (FNIH) [T]  
 [ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6) James, Stephanie (FNIH) [T] [ (b) (6)  
 Colvis, Christine (NIH/NCATS) [E] [ (b) (6) Desrosiers, Betsy [ (b) (6)  
 Hughes, Eric [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) Read, Sarah  
 (NIH/NIAID) [E] [ (b) (6) Hamilton, Holli (OS/ASPR/BARDA) [ (b) (6) ]; Schrag,  
 Stephanie (CDC/DDID/NCIRD/DBD) [ (b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) (b) (6)  
 Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [ (b) (6) Gonzalez, Nina [ (b) (6)  
 (b) (6) (b) (6) Wachtel, Jonathan [ (b) (6)  
 Arvin, Ann [ (b) (6) Anderson, Margaret [ (b) (6) Marston, Hilary  
 (NIH/NIAID) [E] [ (b) (6) Qashu, Felicia (NIH/OD) [E] [ (b) (6) Bethany Stokes  
 [ (b) (6) Paul Gillard [ (b) (6) Michael Watson (x)  
 [ (b) (6) Stratton, Benjamin [ (b) (6) Michael, Nelson  
 [ (b) (6) Young, John [ (b) (6)

**Subject:** ACTIV Vaccines Working Group meeting

**Location:** Webex: <https://nih.webex.com> (b) (6)

**Start:** 5/11/2020 4:00:00 PM

**End:** 5/11/2020 5:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Santos, Michael (FNIH) [T]; (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6)  
 Arvin, Ann; Beth Bell [ (b) (6) (b) (6) (b) (6) (b) (6) Haynes, Barton;  
 (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier,  
 Nancy (CDC/DDID/NCIRD/OD); Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA); Offit, Paul;  
 (b) (6) Seals, Jonathan (OS/ASPR/BARDA); (b) (6) Tal Zaks

**Optional Attendees:** Kathleen Neuzil, Merlin Robb; Marovich, Mary (NIH/NIAID) [E], Cohen, Myron; Tolman, Brett;  
 (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]  
 (b) (6) (b) (6) (b) (6) (b) (6)  
 Austin, Sarah (NIH/NIAID) [E]; Suhana, Tina (NIH/VRC) [E]; (b) (6) Isabel Ramsey; Parker,  
 Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T];  
 Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis,

Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Hamilton, Hollie (OS/ASPR/BARDA); Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; (b) (6)  
(b) (6) Wachtel, Jonathan; Ann Arvin, Anderson, Margaret; Marston, Hilary  
(NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Bethany Stokes; Paul Gillard; Michael Watson (x); Stratton, Benjamin, Nelson Michael

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**From:** Santos, Michael (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]

**Sent:** 4/15/2020 9:27:47 PM

**To:** Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];  
 (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd];  
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 (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002 mc]; (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aebc9a0d9b96c-NAR5]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fdba4598a57b423d484dcf9f-offit.email]; (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se];  
 (b) (6) Tolman, Brett [ (b) (6) Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr];  
 (b) (6) Corrigan, Angela (NIH/VRC) [F] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83998896b0ce4d23a9e481d87568d20f-corriganar];  
 (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4b79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Hughes, Enc [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; (b) (6) Wachtel, Jonathan (b) (6) Arvin, Ann

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta], Anderson, Margaret  
[ (b) (6) Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]

**Subject:** ACTIV Vaccines Working Group meeting

**Location:** Webex: <https://nih.webex.co> (b) (6)

**Start:** 4/20/2020 1:00:00 PM

**End:** 4/20/2020 2:00:00 PM

**Show Time As:** Tentative

**Required Attendees:** (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann;  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) Haynes, Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER);  
Mascola, John (N H/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Offit, Paul; (b) (6) Seals,  
Jonathan (OS/ASPR/BARDA); (b) (6)  
**Optional Attendees:** Tolman, Brett; (b) (6) Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (N H/NC ) [E];  
(b) (6) (b) (6) (b) (6)  
Corrigan, Angela (NIH/VRC) [F]; (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis  
(NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey  
(FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers,  
Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Gonzalez, N na;  
(b) (6) (b) (6) Wachtel, Jonathan; Ann Arvin; Anderson,  
Margaret; Marston, Hilary (NIH/NIAID) [E]

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**Sent:** 6/4/2020 2:18:34 AM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [ (b) (6) Eisner, Mark [ (b) (6) Gottesdiener, Keith (b) (6) Hughes, Eric [ (b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) LaVange, Lisa [ (b) (6) Levy, Elliot [ (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras], Patel, Naimish (b) (6) ]; Peppercorn, Amanda [ (b) (6) Poole, Mike [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn [ (b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner (b) (6)



CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [ (b) (6) Biggs, Mary [ (b) (6) Butcher, Tina [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencio]; Salathin, Carla [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [ (b) (6) Tolman, Brett [ (b) (6) Alvarez, Rosa [ (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [ (b) (6) Rose Li Central Account [ (b) (6) Anderson, Margaret [ (b) (6) Lucas Smalldon [ (b) (6) Stratton, Benjamin [ (b) (6) Mollica, Linda /US [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, H.lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [ (b) (6) Wung, Peter /US [ (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]

Subject: Materials for ACTIV TX-Clinical Working Group Meeting #9

Attachments: ACTIV\_TX-Clinical\_Working Group Meeting Guide\_20200604.pdf

Dear ACTIV TX-Clinical WG,

Please find attached the slides for tomorrow's meeting which contain the agenda. We will be using this meeting as last week to update on the progress of the master protocol groups and the mAb subteam from the Agent Prioritization group.

Please let us know if there is anything else you feel the team needs to discuss.

Thanks,  
Stacey

**Stacey J. Adam, PhD**

Director, Cancer

Research Partnerships

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**From:** Melencio, Cheryl (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=279E14FA74284158B86087D08B628E6F-MELENCIOC]  
**on behalf of** Wholley, David (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
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**To:** Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Bancel, Stephane [ (b) (6) Carter, Kara [ (b) (6) Cavaleri, Marco [ (b) (6) Cihlar, Tomas [ (b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [ (b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [ (b) (6) Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Do sten, Mikael [ (b) (6) Erbeling, Emily (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Erck, Stan [ (b) (6) Fauci, Anthony (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [ (b) (6) Lane, Cliff (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [ (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [ (b) (6) Pangalos, Mene [ (b) (6) Pao, William [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Paul, Steve [ (b) (6) Perlmutter, Roger [ (b) (6) Plenge, Robert [ (b) (6) Plump, Andy [ (b) (6) Rachel Ramon [ (b) (6) Rouse, Doris [ (b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [ (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Tal ey, Michael [ (b) (6) Tsai, John [ (b) (6) Vessey, Rupert [ (b) (6) ]; Virgin,

Skip [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 Helen Q [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange  
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk,  
 Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group  
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CC: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher  
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 [ (b) (6) Castillejos, Carlos [ (b) (6) FNIH Central Account  
 [ (b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lane, Cliff (NIH/NIAID) [E]  
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]

**Subject:** ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020

**Attachments:** 12.16 ACTIV EC and Leadersh p Team Meeting 20201215\_vF.pdf; 12.16 ACTIV EC and Leadership Team Meeting\_APPENDIX 20201215 vF.pdf; 2020-11-19 ACTIV Leadership Team Meeting\_Summary v3.pdf

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, December 16, 10:00 – 11:30 a.m. Eastern U.S. Time.** The minutes from the November 19 Leadership Team call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

**David Wholley**  
**Senior Vice-President, Research Partnerships**  
**Foundation for the National Institutes of Health**

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*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*

**From:** Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]  
**Sent:** 11/18/2020 10:05:02 PM  
**To:** Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]  
**Subject:** FW: ACTIV Leadership Team Meeting November 19, 2020  
**Attachments:** 11.19 ACTIV Leadership Team Meeting 20201118 vF.pdf; 11.19 ACTIV Leadership Team Meeting 20201118 Appendix.pdf; 2020-10-21 ACTIV Leadership Team Meeting Summary-FINAL.docx; 2020-11-04\_Executive\_Committee\_Meeting\_Summary\_vF.pdf

FYI

**From:** Melencio, Cheryl (FNIH) [T] < (b) (6) > **On Behalf Of** Wholley, David (FNIH) [T]  
**Sent:** Wednesday, November 18, 2020 4:50 PM  
**To:** Austin, Christopher (NIH/NCATS) [E] < (b) (6) > Bancel, Stephane  
< (b) (6) > Carter, Kara < (b) (6) > Cavaleri, Marco  
< (b) (6) > Cihlar, Tomas < (b) (6) > Collins, Francis (NIH/OD) [E]  
< (b) (6) > Corey, Larry < (b) (6) > Culp, Michelle (NIH/OD) [E] < (b) (6) >  
Victoria Davey < (b) (6) > Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) > Dolsten, Mikael  
< (b) (6) > Erbeling, Emily (NIH/NIAID) [E] < (b) (6) > Erck, Stan  
< (b) (6) > Fauci, Anthony (NIH/NIAID) [E] < (b) (6) > Freire, Maria (FNIH) [T]  
< (b) (6) > Gadbois, Ellen (NIH/OD) [E] < (b) (6) > Gibbons, Gary (NIH/NHLBI) [E]  
< (b) (6) > Hudson, Thomas < (b) (6) > James, Stephanie (FNIH) [T]  
< (b) (6) > Johnson, Robert (OS/ASPR/BARDA) < (b) (6) > Kramer, Lynn  
< (b) (6) > Lane, Cliff (NIH/NIAID) [E] < (b) (6) > Lepore, John < (b) (6) >  
Marks, Peter (FDA/CBER) < (b) (6) > Marston, Hilary (NIH/NIAID) [E] < (b) (6) >  
Mascola, John (NIH/VRC) [E] < (b) (6) > Meeker, David < (b) (6) > Menetski, Joseph  
(FNIH) [T] < (b) (6) > Messonnier, Nancy (CDC/DDID/NCIRD/OD) < (b) (6) > Pandya, Hitesh  
< (b) (6) > Pangalos, Mene < (b) (6) > Pao, William  
< (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) > Paul, Steve < (b) (6) >  
Perlmutter, Roger < (b) (6) > Plenge, Robert < (b) (6) > Plump, Andy  
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Michael (FNIH) [T] < (b) (6) > Skovronsky, Daniel < (b) (6) > Stein, Peter (FDA/CDER)  
< (b) (6) > Stoffels, Paul < (b) (6) > Tabak, Lawrence (NIH/OD) [E]  
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Rupert < (b) (6) > Virgin, Skip < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) >  
Woodcock, Janet (FDA/CDER) < (b) (6) > Young, John < (b) (6) > Colvis,  
Christine (NIH/NCATS) [E] < (b) (6) > Desrosiers, Betsy < (b) (6) > Eric  
Hughes < (b) (6) > Jansen, Kathrin < (b) (6) > Kurilla, Michael (NIH/NCATS) [E]  
< (b) (6) > Lowy, Douglas (NCI) < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) >  
Young, John < (b) (6) > John Lepore < (b) (6) > Grant, Sarah  
< (b) (6) >  
**Cc:** Adam, Stacey (FNIH) [T] < (b) (6) > Margaret Anderson < (b) (6) > Appell, Evan  
< (b) (6) > Chen, Helen Q. < (b) (6) > Connelly, Sarah < (b) (6) >  
Gonzalez, Nina < (b) (6) > Hawk, Harrison < (b) (6) > Mendelson, Jesse  
< (b) (6) > Menetski, Joseph (FNIH) [T] < (b) (6) > Santos, Michael (FNIH) [T]  
< (b) (6) > asorosa < (b) (6) > Stratton, Benjamin < (b) (6) > btolman  
< (b) (6) > Tountas, Karen (FNIH) [T] < (b) (6) > Wachtel, Jonathan  
< (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Anderson, James (NIH/OD) [E]  
< (b) (6) > Burklow, John (NIH/OD) [E] < (b) (6) > Carluccio, Dana  
< (b) (6) > Castillejos, Carlos < (b) (6) > FNIH Central Account



< (b) (6) Hallett, Adrienne (NIH/OD) [E] < (b) (6) Lane, Cliff (NIH/NIAID) [E]  
< (b) (6) Myles, Renate (NIH/OD) [E] < (b) (6) Parker, Ashley (NIH/OD) [E]  
< (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Wolinetz, Carrie (NIH/OD) [E]  
< (b) (6) Gorman, Greta (FNIH) [T] < (b) (6) Meltzer, Abbey (FNIH) [T]  
< (b) (6)

**Subject:** ACTIV Leadership Team Meeting November 19, 2020

Dear AMP Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Thursday, November 19 12:00 PM – 1:00 PM Eastern U.S. Time.** The minutes from the October 21 Leadership Team call as well as the minutes from the November 4 Executive Committee call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health  
(b) (6)

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**From:** Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]  
**Sent:** 6/8/2020 8:57:42 PM  
**To:** Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]  
**CC:** Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak], Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]  
**Subject:** RE: another member for ACTIV Clinical Trial Capacity Working Group

Hi Karen,

I hope you are well and had a great weekend!

I think FNIH has developed a process for obtaining permissions for future participants which includes asking via email after they've indicated participation with the POC – cc'ing your very own Cheryl to confirm and who's been super helpful.

Also cc'ing Renate and Lauren Brodd for awareness only. Lauren will be working closely with me and Renate, NIH OD to assist with keeping the NIH website for ACTIV up to date.

Thanks again,  
Ashley

**From:** Tountas, Karen (FNIH) [T] <[REDACTED]> (b) (6)  
**Sent:** Monday, June 8, 2020 4:40 PM  
**To:** Parker, Ashley (NIH/OD) [E] <[REDACTED]> (b) (6)  
**Cc:** Meltzer, Abbey (FNIH) [T] <[REDACTED]> (b) (6)  
**Subject:** another member for ACTIV Clinical Trial Capacity Working Group

Hi Ashley,

I hope you had a nice weekend. Please note that the CT Capacity Working Group has a new member from AstraZeneca.

- Therese Takas  
Director, Clinical Operations  
AstraZeneca

Her email contact to obtain permission to list her on the NIH ACTIV website is [REDACTED] (b) (6)

Many thanks!  
Karen

Karen H. Tountas, PhD  
Scientific Program Manager  
Foundation for the National Institutes of Health  
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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

**Sent:** 10/31/2020 1:58:22 AM

**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [ (b) (6) Eisner, Mark [ (b) (6) Gottesdiener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) LaVange, Lisa [ (b) (6) Levy, Elliot [ (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Patel, Naimish (b) (6) Peppercorn, Amanda [ (b) (6) Poole, Mike [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [ (b) (6) Garner, Carl (b) (6) : Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dc8c847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [ (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

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CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7248415bb86087d08b628e6f-melencioc]; Salathin, Carla | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio | (b) (6) Rose Li Central Account | (b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]. Lucas Smal don [Lucas.Small don@roseliassociates.com]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; (b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c289105913411a3ed28f929042aad-RUBIND.fda]; Marston, H lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) | (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03b3cf32930-walkerp1]; Bethany Stokes | (b) (6) asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]

**Subject:** Summary of the ACTIV Therapeutics-Clinical Working Group Meeting

**Attachments:** 2020-10-29\_TX-Clinical\_WG\_Meeting\_Summary.pdf

Dear ACTIV TX-Clinical WG,

Please find attached the summary of our meeting yesterday. If you have any additions or amendments, please let me know.

Thanks,  
Stacey

**Stacey J. Adam, PhD**

Director, Cancer

Research Partnerships

**Foundation for the National Institutes of Health**

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Bascles, Lionel (b) (6)

Cohen, Myron (b) (6)

Corey, Larry (b) (6)

Desrosiers, Betsy (b) (6)

Dickens, Jim (NIH/NCATS) [C] (b) (6)

Doroshov, James (NIH/NCI) [E] (b) (6)

Goff, David (NIH/NHLBI) [E] (b) (6)

Heaton, Penny (b) (6)

King, James (b) (6)

Kurilla, Mike (b) (6)

Nayak, Seema (NIH/NIAID) [E] (b) (6)

Parker, Ashley (NIH/OD) [E] (b) (6)

Payton, Manzine (b) (6)

Resnansky, Laura (b) (6)

Srinivasan, Badhri (b) (6)

Stein, Peter (FDA/CDER) (b) (6)

Tountas, Karen (FNIH) [T] (b) (6)

Vincent, Mike (b) (6)

Wachtel, Jonathan (b) (6)

Woodcock, Janet (FDA/CDER) (b) (6)

From: LaVange, Lisa M [ (b) (6) ]  
Sent: 1/21/2021 4:24:14 PM  
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [ (b) (6) ] Gottesdiener, Keith [ (b) (6) ] Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) ] Levy, Elliot [ (b) (6) ] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) ] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [ (b) (6) ] Peppercorn, Amanda [ (b) (6) ] Poole, Mike [ (b) (6) ] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn [ (b) (6) ] Garner, Carl [ (b) (6) ] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cfff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner

[ (b) (6) Bergel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbergel]; Phillips, L Revell CIV DTRA RD (USA) [ (b) (6) Petrovick, Martha - 0449 - MITLL [ (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Wung, Peter /US [ (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [ (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [ (b) (6) Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact\_f12]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]

Subject: Re: Master Protocol Development and Agent Prioritization Manuscripts for ACTIV TX-Clinical Comment

Great work getting both manuscripts to this point, Stacey!  
Lisa

From: Adam, Stacey (FNIH) [T] < (b) (6) >  
Sent: Wednesday, January 20, 2021 10:57 PM  
To: Bozzette, Sam (NIH/NCATS) [E] < (b) (6) > Butterson, Joan < (b) (6) > De Claro, R Angelo (FDA/CDER) < (b) (6) > Draghia-Akli, Ruxandra < (b) (6) > Gottesdiener, Keith < (b) (6) > Eric Hughes < (b) (6) > Judy Currier < (b) (6) > Kim, Elizabeth < (b) (6) > LaVange, Lisa M < (b) (6) > Levy, Elliot < (b) (6) > Mellors, John W < (b) (6) > Menon, Sandeep < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) > Patel, Naimish < (b) (6) > Peppercorn, Amanda < (b) (6) > Poole, Mike < (b) (6) > Proshan, Michael (NIH/NIAID) [E] < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Shen, Yuan Li (FDA/CDER) < (b) (6) > Stein, Peter (FDA/CDER) < (b) (6) > > Wholley, David (FNIH) [T] < (b) (6) > Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) > Collins, Sylva (FDA/CDER) < (b) (6) > Amanda Peppercorn < (b) (6) > Garner, Carl < (b) (6) > Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) > Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) > Timothy Burgess < (b) (6) > Reineck, Lora (NIH/NHLBI) [E] < (b) (6) > Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6) > Rosenberg, Yves (NIH/NHLBI) [E] < (b) (6) > Goff, David (NIH/NHLBI) [E] < (b) (6) > Brown, Jeremy (NIH/NINDS) [E] < (b) (6) > Gadbois, Ellen (NIH/OD) [E] < (b) (6) > Culp, Michelle (NIH/OD) [E] < (b) (6) > Jacqueline Kirchner

< (b) (6) Beigel, John (NIH) [E] < (b) (6) Phillips, L Revell CIV DTRA  
RD (USA) < (b) (6) Petrovick, Martha - 0449 - MITLL < (b) (6) (b) (6)  
< (b) (6) Sizemore, Christine (NIH/FIC) [E] < (b) (6)  
Cc: Colvis, Christine (NIH/NCATS) [E] < (b) (6) Young, John < (b) (6) Menetski,  
Joseph (FNIH) [T] < (b) (6) Patterson, Amy (NIH/NHLBI) [E] < (b) (6) Rubin, Daniel B.  
(FDA/CDER) < (b) (6) Marston, Hilary (NIH/NIAID) [E] < (b) (6) Chen, Helen  
< (b) (6) Wung, Peter /US < (b) (6) Hoots, W. Keith (NIH/NHLBI) [E]  
< (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E] < (b) (6) Hone, David M (Dave) CIV  
DTRA J9 (USA) < (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)  
< (b) (6) Sorosa, Alex < (b) (6) Lumsden, Joanne (NIH/NCATS) [C]  
< (b) (6) Lerner, Andrea (NIH/NIAID) [E] < (b) (6) Embry, Alan (NIH/NIAID) [E]  
< (b) (6)

**Subject:** Master Protocol Development and Agent Prioritization Manuscripts for ACTIV TX-Clinical Comment

**CONFIDENTIAL – DO NOT SHARE BEYOND GROUP**

Dear ACTIV TX-Clinical WG,

As discussed on last week's call, I am now distributing the current 90% finalized drafts of the Master Protocol Development and Agent Prioritization manuscripts for this group's review and comment. Please find the manuscripts at these links:

**Agent Prioritization:**

[https://docs.google.com/document/d/1w\\_wKs1\\_bX2E\\_pdfmcXvz\\_0qW2cMeyDw0RqUu1wMU2vF/edit](https://docs.google.com/document/d/1w_wKs1_bX2E_pdfmcXvz_0qW2cMeyDw0RqUu1wMU2vF/edit)

**Master Protocol Development:**

[https://docs.google.com/document/d/1nIZT4\\_rPR6v1lbtCEdnE2hJumo6GbsiQu85aW7Pd0xGU/edit](https://docs.google.com/document/d/1nIZT4_rPR6v1lbtCEdnE2hJumo6GbsiQu85aW7Pd0xGU/edit)

We would ask that the team members here review the document to ensure that you feel it accurately reflects the process and efforts of this WG. ***We would ask that the group focus on any major comments that you feel are "critical" to the manuscript. We would ask that you not wordsmith or refine for style at this point, as each of these documents have been through about ~10 of your colleagues for drafting, review, and refinement.***

If you do have suggestions, please follow the instructions at the top of the Google document in green to turn on suggestions in the document before you edit. **If you do choose to comment, please ensure that you have all suggestions returned by a week from today on Wednesday, January 27<sup>th</sup> at 5pm ET.**

Finally, we would ask that you do not share these manuscripts with anyone outside of this distribution list at this time. They are still in draft phase and confidential, so we do not wish to hurt our chance of publication by having them made public to early and in their unfinished form.

Thank you in advance for your assistance with this effort.

Kind regards,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
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**From:** (b) (6) | (b) (6)  
**Sent:** 6/10/2020 8:42:37 AM  
**To:** Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]  
**Subject:** Fwd: Agenda and materials for the Protective Immune Responses Sub-Group meeting  
**Attachments:** image001.jpg; ATT00001.htm; image002.jpg; ATT00002.htm; image003.jpg; ATT00003.htm; image004.jpg; ATT00004.htm; Assay WG Tracker Updated 6-4.xlsx; ATT00005.htm

Hi Chris,

Forwarding the information for the vaccines subgroup meeting taking place at 2:30pm today and follow up conversations next week with Janet on USG assay development— thought others particularly NCATS may want to participate and not currently represented on the protective immune response SG.

Cc'ing Cliff for awareness — seems there are contacts for NIAID.

Best,  
Ashley

Begin forwarded message:

**From:** "Santos, Michael (FNIH) [T]" (b) (6) >  
**Date:** June 9, 2020 at 10:59:53 PM EDT  
**To:** (b) (6)  
" (b) (6) < (b) (6) "Gruber, Marion (FDA/CBER)"  
(b) (6) , "Marks, Peter (FDA/CBER)" (b) (6)  
(b) (6) (b) (6) < (b) (6) "Arvin, Ann"  
< (b) (6) Nelson Michael < (b) (6) "Bett, Andrew J"  
(b) (6) "Gilbert PhD, Peter B" (b) (6) >, "Kathleen Neuzil"  
< (b) (6) "Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)"  
(b) (6) >, "Thornburg, Natalie (CDC/DDID/NCIRD/DVD)" < (b) (6)  
Greg Glenn (b) (6) , Cavaleri Marco (b) (6) >, "Kelly, Beth"  
(b) (6)  
**Cc:** "Tolman, Brett" (b) (6)  
(b) (6) < (b) (6) >, Jeneffer Haynes (b) (6)  
(b) (6) >, "Alvarez, Rosa Maria" (b) (6)  
"Menetski, Joseph (FNIH) [T]" (b) (6)  
"Wholley, David (FNIH) [T]" (b) (6) "Parker, Ashley (NIH/OD) [E]"  
(b) (6) Brian Rosen (b) (6) >, Cheryl Keech (b) (6)  
**Subject:** Agenda and materials for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting at 2:30pm ET (11:30am PT / 6:30pm CEST).

Last week we were fortunate to have Marco Cavaleri present and lead a discussion on EMA regulatory pathways. Development of a table of those pathways analogous to the table developed for FDA pathways is underway.

At this meeting we will return to the topics from two weeks ago: (1) reaching out to collect information on potential signals of human immunity and (2) inter-comparability of immunogenicity assays and centralized labs.

Since that meeting Ann and Mark Davis discussed the first topic, and reached out to Dan Rotrosen (Director of the Division of Allergy, Immunology, and Transplantation at NIAID). He is unfortunately unable to join this meeting, but we will discuss the categories of information we would like to collect and the potential process for doing so.

On the second topic, we reached out to Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them.

Please let us know if you have any questions or suggestions.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Wednesday, June 3, 2020 11:30 PM  
**Subject:** Notes from yesterday's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting, and particular thanks to Marco for the excellent presentation and discussion.

Meeting notes are attached, with the meeting materials are embedded. The key action item is developing a table of EMA pathways analogous to the one that we previously developed with Marion's input and review for FDA pathways.

Please reach out with any additions or edits to the notes, questions, or suggestions.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Monday, June 1, 2020 1:04 PM  
**Subject:** Agenda and materials for the Protective Immune Responses Sub-Group meeting tomorrow (Tuesday)

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting tomorrow (Tuesday) at 8am ET (5am PT / 2pm CEST). We are very sorry for the extremely early start PT.



The main agenda item is to discuss EMA and member state regulatory pathways to vaccine use and approval. Marco will lead the discussion. He previously shared a set of presentation slides (re-attached here). We are also re-attaching the table on FDA pathways that we circulated previously.

Please let us know if you have any questions or suggestions.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Thursday, May 28, 2020 12:57 PM  
**Subject:** Notes and next steps from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting. Notes are attached.

There were two key areas for next steps that we identified in the meeting:

- Potential signals of human immunity:
  - Develop specifics of what we are looking for from immunology research
  - Ask the WG and other contacts for suggestions of researchers/organizations worth reaching out to
  - Reach out and collect information and contacts to engage with the WG (in presentations or other formats)
- Inter-comparability of immunogenicity assays / centralized labs
  - Reach out to NIAID to learn more about planned centralized lab capabilities and timing

Ann kindly followed up with an initial set of recommendations for the first area. We'll be following up to develop the list of information that we'd like to gather and to discuss how to prioritize whom we reach out to. We'll reach out to NIAID and report back on the second area.

We think these topics will form the basis for future discussions, but we are also trying to schedule a meeting for a time when we can have a discussion about the EMA regulatory pathways with Marco, to complement the conversations we have had on FDA pathways. We hope to have an invite for that out soon.

As always, please reach out with any additional input on the notes, questions, or suggestions for future directions for this group.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Tuesday, May 26, 2020 11:42 PM  
**Subject:** Agenda for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Tuesday, May 26, 2020 12:19 AM  
**Subject:** Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Tuesday, May 19, 2020 8:56 AM  
**Subject:** Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,  
Brett and Mike

**Michael Santos, PhD**  
Associate Vice President, Science  
**Foundation for the National Institutes of Health**  
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**From:** Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]  
**Sent:** 5/7/2020 3:19:46 AM  
**To:** (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowydw]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Haynes, Barton (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002 mc]; (b) (6) (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VR) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) [ (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aebc9a0d9b96c-NAR5]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fde4598a57b423d484dcf9f-offit.email], (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) Tal Zaks [ (b) (6) Tolman, Brett [ (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; (b) (6) (b) (6) (b) (6) Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4b71db-johnsonr]; Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; (b) (6) (b) (6) (b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron\_cohen], Douoguih, Macaya [JRDUS] [ (b) (6) Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Gilbert PhD, Peter B [ (b) (6) Paul Gillard [ (b) (6) (b) (6) Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda], Gurunathan, Sanjay /US [ (b) (6) Hamilton, Holli (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamit]; (b) (6) Ledgerwood, Julie (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dc9f31ded594eff8ac506d2c4103c15-ledgerwood], Leyssen, Maarten [JRDNL] [ (b) (6) Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com]; Robb, Merlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17bbdb1e858542e7b5959ec7aeb7679a-mrobb.hivre]; (b) (6) Michael Watson (x) [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; (b) (6) (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [ (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Kim, Elizabeth [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Stratton, Benjamin [ (b) (6)

**Subject:** REVIEW REQUESTED. Covid-19 human challenge model perspective outline; also Vaccines WG meeting notes

**Attachments:** SARS-CoV-2 Controlled Human Infection Model in Support of Preventive Vaccines Outline.docx; controlled human infection model references.zip; 2020-05-05 Working Group meeting Summary Notes.docx

Dear Vaccines Working Group (and cc'ing other Sub-Group members),

Thank you for your participation in yesterday's Vaccines Working Group meeting. Summary notes kindly prepared by the science writer that supports our group are attached. If you have any additions or edits, please feel free to pass them along.

As we discussed at the meeting, an important new deliverable for our Working Group is a perspective on the scientific and operational obstacles for developing a COVID-19 human challenge model on a relevant timescale. A small team from the Vaccine Clinical Trials Sub-Group has taken on that responsibility, with our gratitude.

**Please review the attached outline.** The team has a particular question about how much substantiation of the points being made is necessary. The team is also contemplating which audiences to target and the best ways to reach them. **If you have suggestions or feedback on the outline, or perspectives on these questions, please share them with us.** Existing papers on this topic are attached in the zip file for your reference. This will be an important agenda topic at our next Working Group meeting on Monday, May 11, 12pm ET (9am PT / 6pm CEST).

We look forward to continued engagement as we forge ahead on the path to support accelerated vaccine development. Please reach out anytime with questions or suggestions.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]

**Sent:** Tuesday, May 5, 2020 2:44 AM

**Subject:** Agenda and Materials for ACTIV Vaccines Working Group meeting: Today, 5 May

Dear Vaccines Working Group,

We are looking forward to our next Vaccines Working Group meeting with you, today (Tuesday) at 12pm ET (9am PT / 6pm CEST). The key agenda items for our meeting are:

- Review new mandates for the Working Group
- Discuss pathways to approval/authorization using correlates and other evidence
- Share ACTIV external communications approach

The slides that we will use during the meeting are attached, with some additional slides drawn from the presentation Marion Gruber shared (attached in full in Friday's notes) in an appendix for reference.

We also want to share an update related to the first agenda item. The Vaccines Clinical Trials Sub-Group met for the first time yesterday (Monday). Much as we anticipate the master protocol trial doing, we rapidly enrolled participants (though perhaps with limited informed consent) in this Sub-Group; the roster as of today is attached, with some additional invitations pending. We have also attached the notes from that meeting.

As always, please do not hesitate to reach out with any input or questions.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Sunday, May 3, 2020 5:45 PM  
**Subject:** Vaccines Working Group important update: Clinical Trial plans

Dear Vaccines Working Group,

Yesterday evening there was an exciting expansion of the opportunity for the Vaccines Working Group to contribute to accelerating vaccine development. We learned that there will be US government funding for a master protocol phase 2/3 adaptive vaccine efficacy trial, with provisions to add and drop vaccine candidate arms over time.

The Clinical Trial Sub-Group (slight name change) will be tasked with supporting this master protocol trial, including the protocol and the networks/sites implementation. The goal is to have this trial ready to start by July 1, though there may be an opportunity to start in June if the work can be completed by then.

This is a significant expansion of scope for the Sub-Group. Given the magnitude of this responsibility, we will be asking for additional representation on the Sub-Group and pulling in expertise, including some of the master protocols experts that have been writing the ACTIV therapeutics protocols. The first meeting of the Sub-Group is tomorrow at 10am ET (7am PT / 4pm CEST).

We will also discuss this at the Vaccines Working Group meeting on Tuesday at 12pm ET (9am PT / 6pm CEST). Please don't hesitate to reach out with any questions.

Best regards,  
Mike, for the Vaccines Working Group

Michael Santos, PhD  
Associate Vice President, Science  
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(b) (6) [fnihi.org](https://fnihi.org)  
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**From:** Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 5/29/2020 7:25:11 PM  
**To:** (b) (6) (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E]  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];  
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E]  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [E]  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras];  
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas  
(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar  
[ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6)  
**CC:** Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hughes, Eric  
[ (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Cutillo, Christine (NIH/NCATS) [E]  
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[ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E]  
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[ (b) (6) Kim, Elizabeth [ (b) (6) Tolman, Brett [ (b) (6) Wachtel,



Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) Diamond, Michael  
(b) (6) ]; Rose Li (b) (6) Dana Carluccio  
(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange  
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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[ (b) (6) Dave Frankowski (b) (6) Baric, Toni C  
[ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative  
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint  
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]; Stratton, Benjamin  
[ (b) (6)

**Subject:** RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

Please find the minutes to our meeting on Wednesday. Let me know if you have any questions or concerns with these.

Thank you,

Joe

-----Original Appointment-----

**From:** Menetski, Joseph (FNIH) [T]

**Sent:** Tuesday, April 14, 2020 6:43 PM

**To:** (b) (6) (b) (6) (b) (6) Menetski, Joseph (FNIH) [T]; Hild,  
Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis  
(NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD)  
[E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)  
**Cc:** Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Gonzalez, Nina; Cutillo, Christine (NIH/NCATS) [E]; Simon, Dina (NIH/OD)  
[C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine  
(NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah  
(NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH)  
[T]; A varez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael;  
Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Burrus-Shaw, Cyndi  
(NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint  
(NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin  
**Subject:** ACTIV Preclinical working group (Tuesday meeting)  
**When:** Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).  
**Where:** <https://fnih.zoom.us/j/> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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(b) (6)

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US (Tacoma)

US (Houston)

Meeting ID: (b) (6)

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Find your local number: <https://fnlh.zoom.us> (b) (6)

**From:** Tolman, Brett [ (b) (6) ]  
**Sent:** 11/18/2020 8:13:23 PM  
**To:** Tolman, Brett [ (b) (6) ] McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD)  
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=94d2e362b03243568fa31c3d23550095-xdf4];  
 (b) (6) (b) (6) (b) (6) Cohen, Myron  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 (b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 (b) (6) Hamilton, Hollie (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative  
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Hollie.Hamil];  
 (b) (6) (b) (6) Ledgerwood, Julie (NIH/NIAID) [E]  
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dc9f31ded594eff8ac506d2c4103c15-ledgerwood];  
 (b) (6) (b) (6) Lowy, Douglas (NIH/NCI) [E]  
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Marks, Peter (FDA/CBER)  
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marovich, Mary  
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643acc6347728dbaeb-marovichma]; Mascola, John  
 (NIH/VRCA) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 (b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Offit, Paul  
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Laurent Humeau  
 [ (b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative  
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 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [ (b) (6) (b) (6) Greg Glenn [ (b) (6)  
 (b) (6) Gebo, Kelly (NIH/OD) [G] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=009cf99ae63f4f71b5b1204a73ded609-geboka]; Jacqueline Miller  
 [ (b) (6) François P Roman [ (b) (6) Culp, Michelle (NIH/OD) [E]  
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Marten, Stacey  
 (CDC/DDID/NCEZID/DVBD) [/o=ExchangeLabs/ou=Exchange Administrative Group  
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(FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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[/o=ExchangeLabs/ou=Exchange Administrative Group  
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(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9fa34dbee5794c34b94ee2a55c9dc51e-Richard.Gor]; Johnson, Robert  
(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
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(DPH) [ (b) (6) mmdavis [/o=ExchangeLabs/ou=Exchange Administrative Group  
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Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
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(b) (6) (b) (6) Antonio Lanzavecchia (b) (6)  
CC: (b) (6) (b) (6) (b) (6)  
(b) (6) Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary  
(NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Soriano Osejo, Douglas  
[ (b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Sitar, Sandra (NIH/VRC) [C] [/o=ExchangeLabs/ou=Exchange  
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Tina (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A.  
[ (b) (6) Isabel Ramsey [ (b) (6) Sridhar, Saranya /US  
(b) (6) Brian Rosen [ (b) (6) Cheryl Keech [ (b) (6) Sadoff,  
Jerald [JRDUS] [ (b) (6) Michael, Nelson [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=05b9ca6b24634974b7aeb3fcaead1623-nmichael.hj]; Kayvon Modjarrad  
[ (b) (6) Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative  
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Van Hoof, Johan  
[JRDBE] [ (b) (6) Van Tulden, Karin [JRDBE] (b) (6)  
(b) (6) Shannon Devine [Shannon. (b) (6) Jeneffer Haynes  
(b) (6) Vivek Shinde [ (b) (6) Kathleen Callahan [ (b) (6)  
Brown ScD, Elizabeth R [erb (b) (6) Lindsey, Nicole (CDC/DDID/NCEZID/DVBD)  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ffab2bf06a684c9ea822683392719418-frd3]; Kublin MD, MPH, James  
(b) (6) Stoddard, Jeffrey [JRDUS] (b) (6) ]; David Vaughn  
(b) (6)

**Subject:** ACTIV Vaccines Clinical Trials Sub-Group Meeting  
**Attachments:** Agenda for the Vaccines Clinical Trials Sub-Group meeting tomorrow  
**Location:** https://deloitte.zoom. (b) (6)

**Start:** 11/30/2020 5:00:00 PM  
**End:** 11/30/2020 6:00:00 PM

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Recurrence: (none)

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US (San Jose)

US

US

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**From:** Prabha Fernandes (b) (6)  
**Sent:** 5/29/2020 7:31:05 PM  
**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6)  
(b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa];  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];  
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas' (b) (6)  
Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; 'Tomas Cihlar' (b) (6)  
'Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)' [ (b) (6)  
**CC:** Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; 'Hughes, Eric' (b) (6)  
Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Cuttillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cuttilloc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; 'Desrosiers, Betsy' (b) (6)  
'Jansen, Kathrin' (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; 'Alvarez, Rosa Maria' (b) (6)  
'Kim, Elizabeth' [ (b) (6) 'Tolman, Brett' [ (b) (6)

'Wachtel, Jonathan' [ (b) (6) 'Prabhavathi Fernandes' (b) (6) 'Diamond,  
Michael' [ (b) (6) 'Rose Li' (b) (6) 'Dana Carluccio'  
[ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange  
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos];  
Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi  
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; 'Rodriguez, Robin D'  
[ (b) (6) 'Dave Frankowski' [ (b) (6) 'Baric, Toni C'  
[ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative  
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint  
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]; 'Stratton, Benjamin'  
[ (b) (6)

**Subject:** RE: ACTIV Preclinical working group (Tuesday meeting)

**Attachments:** GC376 A vet feline infectious peritonitis Anivive .pdf; GC376 JJ Virology 2015-Kim-feine coronavirus1 - Copy.pdf

Hi Joe,

When we prioritize re-purposed drugs..

Should we should include vet products. Anvive has announced it data on SARS CoV2.. they have been developing the  
compound for feline infectious peritonitis. Protease inhibitor.

Oral product.

Selectivity index is great..

Attached FYI in case you have not seen.

Regards,

Prabha

**From:** Menetski, Joseph (FNIH) [T] < (b) (6) >

**Sent:** Friday, May 29, 2020 3:25 PM

**To:** (b) (6) (b) (6) david.j. (b) (6) Hild, Sheri (NIH/OD) [E]  
< (b) (6) (b) (6) Annaliesa. (b) (6) kara. (b) (6) >  
(b) (6) (b) (6) Baric, Ralph < (b) (6) (b) (6) Ottinger,  
Elizabeth (NIH/NCATS) [E] < (b) (6) Colvis, Christine (NIH/NCATS) [E] < (b) (6) >  
Hewitt, Judith (NIH/NIAID) [E] < (b) (6) Deming, Damon (FDA/CDER) < (b) (6) >  
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]  
< (b) (6) (b) (6) Adams, Peter (OS/ASPR/BARDA)  
< (b) (6) Rao, Srinivas < (b) (6) Qashu, Felicia (NIH/OD) [E]  
< (b) (6) Tomas Cihlar < (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID  
(USA) < (b) (6) >  
**Cc:** Gadbois, Ellen (NIH/OD) [E] < (b) (6) Hughes, Eric < (b) (6) Gonzalez, Nina  
< (b) (6) Cutillo, Christine (NIH/NCATS) [E] < (b) (6) Simon, D na (NIH/OD) [C]  
< (b) (6) Wholley, David (FNIH) [T] < (b) (6) Austin, Christopher (NIH/NCATS) [E]  
< (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Colvis, Christine (NIH/NCATS) [E]  
< (b) (6) Desrosiers, Betsy < (b) (6) Jansen, Kathrin  
< (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI)  
< (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6)  
Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) James, Stephanie (FNIH)  
[T] < (b) (6) Alvarez, Rosa Maria < (b) (6) Kim, Elizabeth < (b) (6) Tolman,

Brett < (b) (6) Wachtel, Jonathan < (b) (6) Prabhavathi Fernandes  
< (b) (6) Diamond, Michael < (b) (6) Rose Li  
< (b) (6) Dana Carluccio < (b) (6) Lagos, Enrique (NIH/NCATS) [E]  
< (b) (6) Jonson, Samantha (NIH/NCATS) [E] < (b) (6) Burrus-Shaw, Cyndi  
(NIH/OD) [E] < (b) (6) Rodriguez, Robin D < (b) (6) Dave Frankowski  
< (b) (6) Baric, Toni C < (b) (6) Lowy, Douglas (NIH/NCI) [E]  
< (b) (6) Florence, Clint (NIH/NIAID) [E] < (b) (6) Nancy Haigwood  
< (b) (6) Stratton, Benjamin < (b) (6)

**Subject:** RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

Please find the minutes to our meeting on Wednesday. Let me know if you have any questions or concerns with these.

Thank you,

Joe

-----Original Appointment-----

**From:** Menetski, Joseph (FNIH) [T]

**Sent:** Tuesday, April 14, 2020 6:43 PM

**To:** (b) (6) ; Menetski, Joseph (FNIH) [T]; Hild,  
Sheri (NIH/OD) [E]; (b) (6)

(b) (6) ; Parker, Ashley (NIH/OD) [E]; Collins, Francis  
(NIH/OD) [E], (b) (6) , Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas, Qashu, Felicia (NIH/OD)  
[E]; Tomas Cihlar; Plitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)  
**Cc:** Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Gonzalez, Nina; Cutillo, Christine (NIH/NCATS) [E]; Simon, Dina (NIH/OD)  
[C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine  
(NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah  
(NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH)  
[T]; A varez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael;  
Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Burrus-Shaw, Cyndi  
(NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint  
(NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

**Subject:** ACTIV Preclinical working group (Tuesday meeting)

**When:** Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

**Where:** <https://fnih.zoom.us/> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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US (Houston)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

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**From:** Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]  
**Sent:** 5/12/2020 6:02:20 PM  
**Subject:** \*Call with Dr. Janet Woodcock  
**Attachments:** image001.jpg; image002.jpg; image003.jpg; image004.jpg; image005.png  
**Location:** She will dial you on your iPhone  
  
**Start:** 5/12/2020 9:00:00 PM  
**End:** 5/12/2020 9:10:00 PM  
**Show Time As.** Busy

**Recurrence:** (none)

Will call at 5. Thanks. jw

**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Tuesday, May 12, 2020 1:31 PM  
**To:** Woodcock, Janet < (b) (6) >  
**Subject:** RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

5 pm? (b) (6) if you can. Otherwise after 7 pm is good

**From:** Woodcock, Janet < (b) (6) >  
**Sent:** Tuesday, May 12, 2020 1:08 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6) >  
**Subject:** RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

No have to brief higher ups. Later better. Jwv

---

**From:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Date:** May 12, 2020 at 12:49:32 PM EDT  
**To:** Woodcock, Janet (b) (6)  
**Subject:** RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Yes, I would like that. Can you do 3:30?

**From:** Woodcock, Janet < (b) (6) >  
**Sent:** Tuesday, May 12, 2020 11:28 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Can we discuss before tomorrow? jw

**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Tuesday, May 12, 2020 10:46 AM  
**To:** Collins, Francis S (NIH) (b) (6) >; Stoffels, Paul [JJCUS] (b) (6) >; Fauci, Anthony S (NIH)

COLL0000011098-2517131

< (b) (6) Gibbons, Gary H (NIH) < (b) (6) Woodcock, Janet  
(b) (6) ; Pao, William (b) (6) >; Dolsten, Mikael

Cc: Colvis, Christine M (NIH) (b) (6) >; Desrosiers, Betsy < (b) (6) Hughes,  
Eric (b) (6) ; Read, Sarah W (NIH) (b) (6) Jansen, Kathrin  
(b) (6) Kurilla, Michael G (NIH) (b) (6) Lowry, Douglas R (NIH)  
(b) (6) Young, John (b) (6) Freire, Maria C (NIH) (b) (6) >, Tabak,  
Lawrence A (NIH) (b) (6) Lane, Henry C (NIH) (b) (6) : Parker, Ashley S (NIH)  
(b) (6) Anderson, James M (NIH) (b) (6) >; Austin, Christopher P (NIH)  
(b) (6) >; Wolinetz, Carrie D (NIH) (b) (6)

**Subject:** FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Dear ACTIV Executive Committee Members:

Please see the attached letter from the ACTIV Therapeutics-Clinical Working Group received this morning, for consideration on tomorrow morning's Executive Committee teleconference. While we expect the proposals contained herein will be one major topic of discussion, the purpose of the meeting is to hear from all of the Working Group co-chairs (copied on this note) regarding what is working and where they may be facing challenges in ACTIV, and jointly discuss strategy moving forward.

David

**From:** Adam, Stacey (FNIH) [T] < (b) (6) >

**Sent:** Tuesday, May 12, 2020 9:52 AM

**To:** Wholley, David (FNIH) [T] (b) (6)

**Cc:** Read, Sarah (NIH/NIAID) [E] (b) (6) Eric Hughes < (b) (6) Carlos O Garner  
(b) (6) >; Judy Currier (b) (6) >; Keith Gottesdiener  
(b) (6) Amanda Peppercorn < (b) (6) >; Stein, Peter (FDA/CDER)  
(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) (b) (6)

**Subject:** Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Hi David,

Please find attached a letter from the Therapeutics-Clinical Working Group to the ACTIV Executive Committee for their consideration. Overall, the letter is meant to relate some broad challenges and issues that the Therapeutics-Clinical group thinks the ACTIV PPP is facing, as well as some very specific requests for assistance from the ACTIV EC for our team.

Please relay this to the ACTIV EC for their review. Our group would welcome any feedback they have.

Thanks,  
Stacey

Stacey J. Adam, PhD

Director, Cancer

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 5/15/2020 7:18:50 PM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Judy Currier (b) (6); Eric Hughes (b) (6); LaVange, Lisa M (b) (6); Sandeep Menon (b) (6); Proschan, Michael (NIH/NIAID) [E] (b) (6); Read, Sarah (NIH/NIAID) [E] (b) (6); Price, Dionne (FDA/CDER) (b) (6); Rubin, Daniel B. (FDA/CDER) (b) (6); Farley, John (FDA/CDER) (b) (6); Karen Lynn Price (b) (6); Eron, Joe (b) (6); Javan, Arzhang (NIH/NIAID) [E] (b) (6); Roa, Jhoanna (b) (6); Kim, Peter (NIH/NIAID) [E] (b) (6); Demarcus (b) (6); Tountas, Karen (FNIH) [T] (b) (6); Wachtel, Jonathan (b) (6); Elizabeth Kim (b) (6); Parker, Ashley (NIH/OD) [E] (b) (6); [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa (b) (6); Eron, Joseph J Jr (b) (6); Smith, David (b) (6); Paul Klekotka [klekotka\_paul@lilly.com]; Ajay Nirula [niru (b) (6)]

**Subject:** ACTIV TX-Clinical Master Protocol Outpatient mAbs Writing Team Meeting #1  
**Attachments:** a5401-d03-activ-051620.docx  
**Location:** https://fnih.zoom.us, (b) (6)  
**Start:** 5/18/2020 5:00:00 PM  
**End:** 5/18/2020 6:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; (b) (6); (b) (6); (b) (6); (b) (6); Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6); Kim, Peter (NIH/NIAID) [E]  
**Optional Attendees:** Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka

\*\*\*Updated with New Protocol Version\*\*\*

Dear ACTIV-2 Master Protocol Writing Team,

Thank you all for being willing to get together so quickly. I look forward to the ACTIV and the ACTG teams working together to make this protocol great and get it going quickly.

We will work to get a full list of participants and their roles together for this meeting to distribute. In the meantime, the ACTG team has been kind enough to send the current draft of their protocol for us to start from. They have noted to me that they have removed some agent specific information for confidentiality purposes, but all else should be ready for this group to review and start thinking and commenting on.

Thanks,

Stacey

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To: Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Baric, Ralph [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Ottinger, Elizabeth (NIH/NCATS) [E] [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [ (b) (6) Hewitt, Judith (NIH/NIAID) [E] [ (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter Adams]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a27ea3d34f1e072f8cb7-menetskijp]; (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter Adams]; Rao, Srinivas [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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 [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group  
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Move due to conflict with the ACTIV executive Committee meeting

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**Subject:** ACTIV EC & Working Group Co-Chair Meeting  
**Location:** <https://nih.zoom>. (b) (6)

**Start:** 9/9/2020 1:00:00 PM  
**End:** 9/9/2020 2:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA), Dolsten, M kael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kur Ila, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T], Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T], Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]

**Optional Attendees:** Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Culp, Michelle (N.H/OD) [E], FNIH Central Account; Gadbois, El en (N H/OD) [E], Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas,

Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Ennque (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Tajalli, Ada (NIH/OD) [E]

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**From:** Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 5/5/2020 11:56:17 AM  
**To:** (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph  
[ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];  
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];  
(b) (6) Adams, Peter (OS/ASPR/BARDA) [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [ (b) (6)  
**CC:** Florence, Clint (NIH/NIAID) [E] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Diamond, Michael [ (b) (6) Gonzalez, Nina [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Wholley, David (FNIH) [T] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [ (b) (6) Kim, Elizabeth [ (b) (6) Tolman, Brett [ (b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) Rose Li [ (b) (6) Dana Carluccio [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Simon, Dina (NIH/OD) [C] [ /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [ (b) (6) Dave Frankowski [ (b) (6) Baric, Toni C [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]

**Subject:** Canceled: ACTIV Preclinical working group (Tuesday meeting)

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 5/5/2020 6:00:00 PM

**End:** 5/5/2020 7:00:00 PM

**Show Time As:** Free

**Recurrence:** Weekly  
every Tuesday from 2:00 PM to 3:00 PM

**Required Attendees:** (b) (6) (b) (6) (b) (6) : (b) (6)  
(b) (6) kara. (b) (6) (b) (6) (b) (6) (b) (6)  
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(b) (6) (b) (6) (b) (6) (b) (6) Parker,  
Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E], (b) (6) Adams, Peter  
(OS/ASPR/BARDA); Rao, Srinivas

**Optional Attendees:** Florence, Clint (NIH/NIAID) [E]; Diamond, Michael; Gonzalez, Nina; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]

Cancelling due to the NPRC director's meeting.

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**From:** Tountas Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40c04fef6f1e46f5b750753cd5a14f93-TOUNTASKH]  
**Sent:** 5/21/2020 3:26:14 PM  
**To:** Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel [ (b) (6) Cohen, Myron [ (b) (6) Corey, Larry [ (b) (6) Desrosiers, Betsy [ (b) (6) Dickens, Jim (NIH/NCATS) [C] [ (b) (6) ]; Doroshov, James (NIH/NCI) [E] [ (b) (6) Goff, David (NIH/NHLBI) [E] [ (b) (6) ]; Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) Nayak, Seema (NIH/NIAID) [E] [ (b) (6) Parker, Ashley (NIH/OD) [E] [ (b) (6) Payton, Manizhe (NIH/NIAID) [E] [ (b) (6) Resnansky, Laura [ (b) (6) Srinivasan, Badhri [ (b) (6) Stein, Peter (FDA/CDER) [ (b) (6) Wachtel, Jonathan [ (b) (6) Qashu, Felicia (NIH/OD) [E] [ (b) (6) Vincent, Mike [ (b) (6) ]  
**CC:** Colvis, Christine (NIH/NCATS) [E] [ (b) (6) Jansen, Kathrin [ (b) (6) Lowy, Douglas (NCI) [ (b) (6) Read, Sarah (NIH/NIAID) [E] [ (b) (6) Young, John [ (b) (6) Adam, Stacey (FNIH) [T] [ (b) (6) Anderson, Margaret [ (b) (6) Carluccio, Dana [ (b) (6) Melencio, Cheryl (FNIH) [T] [ (b) (6) Collins, Francis (NIH/OD) [E] [ (b) (6) Gonzalez, Nina [ (b) (6) Heaton, Penny [ (b) (6) James, Stephanie (FNIH) [T] [ (b) (6) Li, Rose [ (b) (6) Menetski, Joseph (FNIH) [T] [ (b) (6) Santos, Michael (FNIH) [T] [ (b) (6) Tuveson, Nancy [ (b) (6) Wholley, David (FNIH) [T] [ (b) (6) ]; Criffield, Robin [ (b) (6) Minnich, Beth [ (b) (6) Katz, Rebecca (NIH/NCATS) [E] [ (b) (6) Stratton, Benjamin [ (b) (6) Tolman, Brett [ (b) (6) Victoria Davey [ (b) (6) Jintanat Ananworanich [ (b) (6) Sizemore, Christine (NIH/FIC) [E] [ (b) (6) Kenny, Dermot [ (b) (6) Weinmann, Gail (NIH/NHLBI) [E] [ (b) (6) Mensah, George (NIH/NHLBI) [E] [ (b) (6) Garner, Carlos [ (b) (6) Denny, Joshua (NIH/OD) [E] [ (b) (6) Reid, Nancy (NIH/OD) [C] [ (b) (6) Gebo, Kelly (NIH/OD) [G] [ (b) (6) Moschetti, Justin (NIH/OD) [E] [ (b) (6) Culp, Michelle (NIH/OD) [E] [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hughes, Eric [ (b) (6) Hamilton, Nancy [ (b) (6) ]

**Subject:** ACTIV Clinical Trial Capacity Working Group - reporting meeting

**Attachments:** Clinical Trial Capacity Working Group Meeting Agenda 05222020 pdf; ACTIV Protocol Tracker 05212020.pdf

**Location:** <https://zoom.us/> (b) (6)

**Start:** 5/22/2020 1:00:00 PM

**End:** 5/22/2020 2:00:00 PM

**Show Time As:** Busy

**Recurrence:** Weekly  
every Tuesday and Friday from 9:00 AM to 10:00 AM

**Required Attendees:** Vincent, Mike; Bascles, Lionel, Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manizhe; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Qashu, Felicia

**Optional Attendees:** Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E]; Garner, Carlos; Denny, Joshua (NIH/OD) [E]; Reid, Nancy (NIH/OD) [C]; Gebo, Kelly (NIH/OD) [G]; Moschetti, Justin (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] [ (b) (6) Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] [ (b) (6) Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich



Dear Colleagues, Attached is the Agenda. Please note that we will be hearing from the *All of Us* program and how they might be useful for implementing ACTIV protocols. In addition, per a request from Tuesday's meeting, attached is the ACTIV Protocol Quick Reference Tracker — thanks to Jonathan and his colleagues for creating this! At present there are three ACTIV protocols, all in the treatment category. CTC Recommendations Committees have been established for the ACTIV-1 and ACTIV-2 protocols to date and integration with the protocol development and lead network operations teams will take place in the very near future. Best regards, Karen

## ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co chairs have agreed that it will be important to hold twice weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response, later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,  
Karen

Karen H. Tountas, PhD  
Scientific Program Manager  
Foundation for the National Institutes of Health

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 4/22/2020 12:57:27 AM  
**To:** Eric Hughes [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [ (b) (6) ]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [ (b) (6) ]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [ (b) (6) ]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [ (b) (6) ]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [ (b) (6) ]  
**CC:** Elizabeth Kim [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskip]; Alvarez, Rosa Maria [ (b) (6) ]; Salathin, Carla [ (b) (6) ]; (b) (6) (b) (6) (b) (6)  
Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [ (b) (6) ]

**Subject:** ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #3  
**Location:** <https://fnih.zoom>. (b) (6)

**Start:** 4/24/2020 6:00:00 PM  
**End:** 4/24/2020 7:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael  
**Optional Attendees:** Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) (b) (6)  
Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon

Dear TX-Clinical Agent Prioritization Subgroup,

This will be our 3<sup>rd</sup> meeting. We will update with materials closer to the call.

Thanks,

Stacey

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**From:** Mellors, John W [ (b) (6) ]  
**Sent:** 5/3/2020 8:04:56 PM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [ (b) (6) ]; Naimish Patel [ (b) (6) ]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [ (b) (6) ]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [ (b) (6) ]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [ (b) (6) ]; Keith Gottesdiener [ (b) (6) ]; Elliott Levy [ (b) (6) ]; Wung, Peter /US [ (b) (6) ]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [ (b) (6) ]  
**CC:** Elizabeth Kim [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla [ (b) (6) ]; Merritt, Gabriella Marie [ (b) (6) ]; Romanowski, Jake [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [Lucas.Smalldon@roseliassociates.com]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]  
**Subject:** RE: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting  
**Attachments:** EMA summary-compassionate-use-remdesivir-gilead\_en.pdf

Useful EMA review of remdesivir. Substrate and weak inhibitor of CYP3A. Not clear what the effect of 3A4 inhibitor would be of complex metabolism.

**From:** Adam, Stacey (FNIH) [T] [mailto: (b) (6) ]  
**Sent:** Sunday, May 3, 2020 2:31 PM  
**To:** Eric Hughes < (b) (6) >; Read, Sarah (NIH/NIAID) [E] < (b) (6) >; Ruxandra Draghia-Akli < (b) (6) >; Mellors, John W < (b) (6) >; Naimish Patel < (b) (6) >; Colvis, Christine (NIH/NCATS) [E] < (b) (6) >; Young, John < (b) (6) >; Stein, Peter (FDA/CDER) < (b) (6) >; Poole, Mike < (b) (6) >; Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) >; Vincent, Michael < (b) (6) >; Keith Gottesdiener < (b) (6) >; Elliott Levy < (b) (6) >; Wung, Peter /US < (b) (6) >; Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) >; Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) >; Carlos O Garner < (b) (6) >  
**Cc:** Elizabeth Kim < (b) (6) >; Menetski, Joseph (FNIH) [T] < (b) (6) >; Salathin, Carla < (b) (6) >; Merritt, Gabriella Marie < (b) (6) >; Romanowski, Jake < (b) (6) >; Parker, Ashley (NIH/OD) [E] < (b) (6) >; Wholley, David (FNIH) [T] < (b) (6) >; Melencio, Cheryl (FNIH) [T] < (b) (6) >; Lucas Smalldon < (b) (6) >; Walker, Paula (NIH/NINDS) [E] < (b) (6) >; Ward, Jackie (NIH/NINDS) [E] < (b) (6) >  
**Subject:** Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting

Hi ACTIV TX-Clinical Prioritization Subgroup members,

Please find attached the final tally of scores for the agents that came through triage in Wave 1. We will use this document for our discussions today.

For those who sent me comments, I did not want to over whelm the score sheet with multiple rows of information. However, I have those and I will include them in the final record for posterity for this round. You can also feel free to bring them up during the discussion if helpful to the group.

Thanks,  
Stacey

**Stacey J. Adam, PhD**  
Director, Cancer  
Research Partnerships

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**Sent:** 5/30/2020 1:01:41 AM  
**To:** Gonzalez, Nina [ (b) (6) ]  
**CC:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Elsaid, Olivia [ (b) (6) ]  
**Subject:** RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30  
**Attachments:** ACTIV Therapeutics 053020.pptx

Hi all,

Thanks, this is an excellent set, though to keep the discussions with Moncef concise, I've moved some of the slides to the Appendix. See current version. I will send this to Janet now too.

One question: when the immunomodulator slide 7 says this:

*All 3 agents have Initial Phase II data or are currently running company-sponsored Phase II trials*

What does that mean? Phase II trials for what application?

Francis

---

**From:** Gonzalez, Nina < (b) (6) >  
**Sent:** Friday, May 29, 2020 8:37 PM  
**To:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Cc:** Adam, Stacey (FNIH) [T] < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Freire, Maria (FNIH) [T] < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) > Elsaid, Olivia < (b) (6) >  
**Subject:** RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi Francis,

See attached the latest version of the slides for the meeting tomorrow.

We'll be on standby for any edits you may have.

Thank you,

Nina

**Nina Gonzalez**  
Deloitte Consulting LLP  
Tel/Direct: (b) (6)

COLL0000020603-2517139

Please consider the environment before printing.

**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Sent:** Friday, May 29, 2020 8:32 PM  
**To:** Wholley, David (FNIH) [T] (b) (6) >  
**Cc:** Adam, Stacey (FNIH) [T] (b) (6) >; Freire, Maria (FNIH) [T] (b) (6) ; Gonzalez, Nina (b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6)  
**Subject:** [EXT] RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hoping these are coming to me soon, as I may want to do some editing -- and then I wanted to run them past Janet tonight.

FC

**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Friday, May 29, 2020 7:41 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] (b) (6) ; Freire, Maria (FNIH) [T] (b) (6) ; Gonzalez, Nina (b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6) ; Freire, Maria (FNIH) [T] (b) (6)  
**Subject:** RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Have seen and offered a few changes to the complete slide deck. They should be coming back to you as soon as Deloitte makes the changes.

**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Sent:** Friday, May 29, 2020 5:59 PM  
**To:** Wholley, David (FNIH) [T] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] (b) (6) >; Freire, Maria (FNIH) [T] (b) (6) ; Gonzalez, Nina (b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6)  
**Subject:** RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note -- has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Friday, May 29, 2020 1:59 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gonzalez, Nina  
(b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6)  
**Subject:** Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here's the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
  - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
  - ACTIV hiVIG (sponsored by NIAID) – in progress
  - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
  - ACTIV-2\* – Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
  - ACTIV-3\* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
  - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) – (Phase II/III) – projected launch late June
  - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August (*if needed, i.e. if agents are not incorporated into mAb protocols*)
    - \* current priority
- [for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)  
[Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
  - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
  - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
  - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
  - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)



- Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
- Protocol is 80% complete
  - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
    - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
  - All three companies have written their sections of the protocols, which are being merged into the master design
- Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- “ACTIV-4” Protocol for anticoagulants
  - Need bullets from NHLBI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley  
 Senior Vice-President, Research Partnerships  
 Foundation for the National Institutes of Health

(b) (6)

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**From:** John Lepore [ (b) (6) ]  
**Sent:** 4/9/2020 12:38:28 AM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**CC:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]  
**Subject:** RE: URGENT: Invitation to join the Vaccines Working Group of the COVID PPP

Dear Francis -

Thank you very much for sponsoring this critical initiative and for enabling GSK to contribute.

Please do reach out if you see any other way we could be of help.

With best wishes -

John

**John Lepore**  
**SVP, Head of Research**

**GSK**  
1250 S. Collegeville Road, Mail Code UP4-4400, Collegeville, PA 19426, US  
**Email** (b) (6)  
**Tel** (b) (6)  
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**From:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Sent:** Wednesday, April 08, 2020 8:27 PM  
**To:** Emmanuel Hanon < (b) (6) >  
**Cc:** Melencio, Cheryl (FNIH) [T] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > John Lepore < (b) (6) >  
**Subject:** URGENT: Invitation to join the Vaccines Working Group of the COVID PPP

EXTERNAL

Dear Dr. Hanon,

Addressing the COVID-19 pandemic is an urgent priority for the entire biomedical research community. Appropriately, the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond. But there is still no proven treatment, and safe and effective vaccines are many months away.

APAR0000012698-2517140

NIH has been working at the forefront of addressing the crisis, including rapidly launching its own clinical trials of therapeutics and a vaccine candidate. But given the seriousness of this global public health crisis, it is time to broaden the response and create a focused public-private partnership with FDA, industry, and academic scientists to further accelerate progress against COVID and the threat of future pandemics. This past Friday I led an initial discussion convened by the Foundation for the National Institutes of Health (FNIH) to decide on the initial research agenda for the partnership. There was broad support from all sectors for this model — with some harkening back to a similar partnership that led to the development of antivirals for HIV/AIDS many years ago. Inspired by the shared embrace of a call to action, we are immediately launching efforts to collaborate in four key areas—accelerating preclinical therapeutic development, optimizing clinical therapeutic development, coordinating clinical trials capacity, and supporting effective vaccine development. Those four areas, and a summary of the meeting, are described in the attached document.

Each area will be powered by a nimble Working Group that includes appropriate domain expertise drawn from among our stakeholders. **You have been recommended to us by John Lepore as a member of the Vaccines Working Group.** The primary objective of this working group is to provide a collaborative framework for advancing vaccine development. I expect this will require a significant investment of your time when I know time is scarce. But these very serious circumstances call for full dedication to action from us all. I am personally committed to doing everything possible to support the execution of this partnership, and would be deeply appreciative if you will contribute your talents to this important effort.

Please direct your response to this invitation by Thursday April 9 (tomorrow! sorry this is such short notice) at 12pm EDT to Cheryl Melencio (b) (6). You may send any questions to Mike Santos (b) (6) at FNIH. A calendar invitation to the initial meeting of the Working Group will be sent out shortly after the response deadline.

I look forward to working with you on this critical effort.

Best,  
Francis S. Collins, M.D., Ph.D.  
Director, NIH

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**Sent:** 5/15/2020 7:27:04 PM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [ (b) (6) Eisner, Mark [ (b) (6) Gottesdiener, Keith (b) (6) Hughes, Eric [ (b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) LaVange, Lisa [ (b) (6) Levy, Elliot [ (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras], Patel, Naimish (b) (6) ]; Peppercorn, Amanda [ (b) (6) Poole, Mike [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [ (b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [ (b) (6) Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]  
**CC:** Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [ (b) (6) Butcher, Tina [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh); Menetski, Joseph (FNIH) [T]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp); James, Stephanie (FNIH)  
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst); Wachtel, Jonathan  
 (b) (6) Tolman, Brett [ (b) (6) Alvarez, Rosa [ (b) (6)  
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d); Dana Carluccio [ (b) (6) Rose  
 Li Central Account [ (b) (6) Anderson, Margaret [ (b) (6) Lucas  
 Smalldon [ (b) (6) Stratton, Benjamin [ (b) (6)  
 (b) (6) Mollica, Linda /US [ (b) (6) Qashu, Felicia (NIH/OD) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm); Patterson, Amy  
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa); Goff, David (NIH/NHLBI) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc); Rubin, Daniel B. (FDA/CDER)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]

**Subject:** ACTIV TX-Clinical Working Group Meeting #7  
**Location:** <https://fnih.zoom>. (b) (6)

**Start:** 5/21/2020 6:00:00 PM  
**End:** 5/21/2020 7:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER) Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith, Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep, Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael, Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]  
**Optional Attendees:** Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Doug as (NCI), Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin, Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose L. Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Rubin, Daniel B.

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**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 9/25/2020 4:57:19 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [ (b) (6) Disbrow, Gary (OS/ASPR/BARDA) [ (b) (6) Dolsten, Mikael [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [ (b) (6) ]; Gibbons, Gary (NIH/NHLBI) [E] [ (b) (6) Marks, Peter (FDA/CBER) [ (b) (6) ]; Pao, William [ (b) (6) Plump, Andrew [ (b) (6) Stoffels, Paul [PStoffe4@its.nj.com]; Woodcock, Janet (FDA/CDER) [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [ (b) (6) Eric Hughes [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) Lowy, Douglas (NCI) [ (b) (6) Read, Sarah (NIH/NIAID) [E] [ (b) (6) Desrosiers, Betsy [ (b) (6) Young, John [ (b) (6)

**CC:** Adam, Stacey (FNIH) [T] [ (b) (6) Alvarez, Rosa Maria [ (b) (6) Margaret Anderson [ (b) (6) Appell, Evan [ (b) (6) Chen, Helen Q. [ (b) (6) Gonzalez, Nina [ (b) (6) Hawk, Harrison [ (b) (6) ]; Mendelson, Jesse [ (b) (6) Menetski, Joseph (FNIH) [T] [ (b) (6) Santos, Michael (FNIH) [T] [ (b) (6) Stratton, Benjamin [ (b) (6) ]; btolman [ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6) Wachtel, Jonathan [ (b) (6) Wholley, David (FNIH) [T] [ (b) (6) ; Barasch, Kimberly (NIH/NIAID) [C] [ (b) (6) ]; Conrad, Patricia (NIH/NIAID) [E] [ (b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [ (b) (6) ]; McManus, Ayanna (NIH/OD) [E] [ (b) (6) Peralta, Mie [ (b) (6) Protasiewicz, Ann [ (b) (6) Thomas, Ashley (FDA/CDER) [ (b) (6) Wood, Gretchen [ (b) (6) Anderson, James (NIH/OD) [E] [ (b) (6) Austin, Christopher [ (b) (6) Burklow, John (NIH/OD) [E] [ (b) (6) Carluccio, Dana [ (b) (6) Castillejos, Carlos [ (b) (6) Culp, Michelle (NIH/OD) [E] [ (b) (6) FNIH Central Account [ (b) (6) Freire, Maria (FNIH) [T] [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois]; Hallett, Adrienne (NIH/OD) [E] [ (b) (6) ]; Lane, Cliff (NIH/NIAID) [E] [ (b) (6) Myles, Renate (NIH/OD) [E] [ (b) (6) Parker, Ashley (NIH/OD) [E] [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [ (b) (6) Wolinetz, Carrie (NIH/OD) [E] [ (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [ (b) (6) Carver, Trea (NIH) [C] [ (b) (6) Hughes, Karen (NIH/OD) [E] [ (b) (6) ], Lagos, Enrique (NIH/NCATS) [E] [ (b) (6) ], Sepulveda, Dorina (FNIH) [T] [ (b) (6) Simon, Dina (NIH/OD) [C] [ (b) (6) Tajalli, Ada (NIH/OD) [E] [ (b) (6) ]; Gorman, Greta (FNIH) [T] [ (b) (6) Meltzer, Abbey (FNIH) [T] [ (b) (6) Togashi, Mieko (NIH/NCI) [E] [ (b) (6) Underwood, Nancy [ (b) (6) Zottoli, Jessica [ (b) (6) Sorosa, Alex [ (b) (6) Connelly, Sarah [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [ (b) (6) Riccobene, Kim [ (b) (6) Hamilton, Nancy [ (b) (6)

**Subject:** ACTIV EC & Working Group Co-Chair Meeting  
**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 11/4/2020 3:00:00 PM  
**End:** 11/4/2020 4:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Melencio, Cheryl (FNIH) [T]; Collins, Francis (NIH/OD) [E], Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael, Fauci, Anthony (NIH/NIAID) [E], Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER), Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John  
**Optional Attendees:** Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Appell, Evan; Chen, Helen; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Menetski, Joseph (FNIH) [T], Santos, Michael (FNIH) [T], Stratton, Ben; Toman, Brett;



Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIH) [C]; Conrad, Patricia (NIH/NIH) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Freire, Mana (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Hal ett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIH) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carne (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Tajalli, Ada (NIH/OD) [E]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Togashi, Meko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jess.ca; Hamilton, Nancy; Sorosa, Alex; Connel y, Sarah; Lowy, Douglas (NIH/NCI) [E]

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

**Sent:** 6/2/2020 2:46:05 PM

**To:** Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [ (b) (6) ]; Amanda Peppercorn [ (b) (6) ]; Breuer, Sebastian [ (b) (6) ]; Martin, Flavius [ (b) (6) ]; Andrew Charles Adams [ (b) (6) ]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Judy Currier [ (b) (6) ]; Tressler, Randall (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Tressler, Randall (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c1978dd53134e13ac736758e8b8756f-tresslerl]; Smith, David [ (b) (6) ]; Jacqueline Kirchner [ (b) (6) ]

**CC:** Chen, Helen Q. [ (b) (6) ]; Payton, Natalie [ (b) (6) ]; Andrew Lucas [ (b) (6) ]; Para [ (b) (6) ]; Dana Carluccio [ (b) (6) ]; Lucas Smalldon [ (b) (6) ]; Rose Li Central Account [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]

**Subject:** Confirmed: ACTIV TX-Clinical Agent Prioritization - mAb Subteam Meeting

**Attachments:** ACTIV\_TX-Clinical\_mAb Sub Team Meeting Agenda 20200602.pdf; Gating Criteria for SARS CoV 2 mAbs moving into Phase II studies 052820.docx; ITPP COVID-19 mAb PREP PEP \_\_Exec Summ.docx

**Location:** <https://nih.zoom>. (

**Start:** 6/2/2020 6:00:00 PM

**End:** 6/2/2020 7:00:00 PM

**Show Time As:** Tentative

**Required Attendees:** Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Amanda Peppercorn; Breuer, Sebastian; Martin, Flavius; Andrew Charles Adams; John Mellors; Marovich, Mary (NIH/NIAID) [E]; Judy Currier; Tressler, Randall (NIH/NIAID) [E]; Smith, David; Jacqueline Kirchner

**Optional Attendees:** Elizabeth Kim; Chen, Helen Q.; Payton, Natalie; Andrew Para; (b) (6) Dana Carluccio; Lucas Smalldon; Rose Li Central Account; Parker, Ashley (NIH/OD) [E]

Dear ACTIV Agent Prioritization – mAb Subteam,

Please find attached the materials for today's meeting, which is confirmed.

1. Meeting agenda
2. Current list of mAb Criteria generated by this team
3. Two documents shared with us by the Gates team about their considerations for mAb for prophylaxis

A representative from Gates will be joining us today, and if we have time at the end we can discuss their effort a bit. However, the main focus of this meeting will be to address the feedback that was shared with this team from the TX-Clinical Working Group from their meeting last week, which is mainly to reduce and refine the criteria to the minimal necessary mAb to enter a Phase 2 trial.

Thanks,  
Stacey

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**From:** Michael Hughes [ (b) (6) ]  
**Sent:** 5/21/2020 3:02:50 PM  
**To:** Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; LaVange, Lisa M [ (b) (6) ]; Eron, Joseph J Jr [ (b) (6) ]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [ (b) (6) ]; Sandeep Menon [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [ (b) (6) ]; smith.davey [ (b) (6) ]; chew.kara [ (b) (6) ]; Wohl, David A [ (b) (6) ]; Fischer, William A. II [ (b) (6) ]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; li.jonathan [ (b) (6) ]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]  
**CC:** DeMarcus, Forrest [ (b) (6) ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) ]; Elizabeth Kim [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; roa.jhoanna [ (b) (6) ]; Smith, David [ (b) (6) ]; Paul Klekotka [ (b) (6) ]; Ajay Nirula [ (b) (6) ]; Elsaid, Olivia [ (b) (6) ]; Robert Jan Benshop [ (b) (6) ]; Lei Shen [ (b) (6) ]  
**Subject:** Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3  
**Attachments:** 5401 Protocol Synopsis 051920v3.docx

Hi All:

The ACTG team was hoping to submit the A5401 protocol tomorrow to the NIAID Clinical Science Review Committee for their review. The protocol design uses standard (widely-used) statistical methods for interim and final analyses but we received the feedback (attached) from ACTIV about moving to fully use Bayesian methods, so wanted to respond and get thoughts back as this is a substantial change --- and would mean that we would not be able to send for CSRC tomorrow.

I have particular concerns about the need to use the Bayesian paradigm, particularly for Phase III. For a given agent, the Phase 3 study is a fairly simple study involving evaluations for safety, clinical symptoms, and the primary outcome measure of hospitalization/death. We proposed to use standard group sequential monitoring methods which are flexible (using the Lan DeMets approach for flexible timing of interim analyses with an O'Brien and Fleming type stopping guideline). I think the seamless phase II to phase 3 aspect of the

design can be incorporated into this flexible approach by just considering the "look" at the data at the end of phase II as one "look" at the phase 3 primary outcome. This provides protection for the Type I error rate for each specific agent. We can overlay a the possibility of a simple futility rule, eg at  $\geq 50\%$  enrollment, to allow stopping for lack of effect (can be justified using a Type II spending boundary, conditional power, or even a Bayesian type rule).

I think this is al quite straightforward. I worry that putting the Phase 3 trial into the Bayesian paradigm gains very little but adds complexity in terms of having to confirm that any Bayesian decision rule does protect Type I error rate for regulatory purposes, and in terms of explaining to many different companies and ultimately to a broad audience. In addition, if the study does go global, it increases the complexity of explaining to IRBs and other review groups.

I would prefer to leave Phase 3 using standard (widely used) statistical methods. I would also favor using standard methods for analysis of Phase 2 data but do agree that Bayesian analyses might also be used for the main efficacy outcome measures to provide an additional perspective in decision-making --- though the main graduation rules (eg observing an absolute 20% reduction in % positive for SARS-CoV-2 at an measurement time, and/or a 20% reduction in mean symptom duration) are straightforward and well-powered.

I would welcome feedback.

Many thanks,  
Michael

---

**From:** Proschan, Michael (NIH/NIAID) [E] <(b) (6)>  
**Sent:** Thursday, May 21, 2020 8:52 AM  
**To:** LaVange, Lisa M; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey, Michael Hughes; (b) (6) Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; (b) (6) kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)  
**Cc:** DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen  
**Subject:** RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

I think the question is whether we could stop early for efficacy as well as stopping early for futility. That could certainly be incorporated if you think there is a realistic possibility of crossing an efficacy boundary after only 50 people. At the halfway point, the O'Brien-Fleming-like spending function boundary for the z-score is close to 3, so you would have to see a very large z-score to stop that early for efficacy.

Mike.

**From:** LaVange, Lisa M <(b) (6)>  
**Sent:** Thursday, May 21, 2020 7:53 AM  
**To:** Eron, Joseph J Jr <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Judy Currier  
<(b) (6)> Eric Hughes <(b) (6)> Sandeep Menon  
<(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah

(NIH/NIAID) [E] < (b) (6) Price, Dionne (FDA/CDER) < (b) (6) Rubin, Daniel B.  
(FDA/CDER) < (b) (6) Farley, John (FDA/CDER) < (b) (6) Karen Lynn Price  
< (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) Wohl, David A < (b) (6) Fischer, William A. II  
< (b) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) Roa, Jhoanna <jroa@s-  
3.com>; (b) (6) Kim, Peter (NIH/NIAID) [E] < (b) (6) Jonathan Li < (b) (6)  
Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) Kozak, Marina (OS/ASPR/BARDA)  
< (b) (6)  
**Cc:** DeMarcus, Forrest < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan  
< (b) (6) Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)  
Jhoanna Roa < (b) (6) Smith, David < (b) (6) Paul Klekotka  
< (b) (6) Ajay Nirula < (b) (6) Elsaid, Olivia < (b) (6) Robert Jan  
Benschop < (b) (6) Lei Shen < (b) (6)  
**Subject:** RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

This seems reasonable to me. We can define any basis that we think will be important for dropping dose arms or entire agents, having little to go on at this point in terms of what best predicts hospitalizations.  
Lisa

**From:** Eron, Joseph J Jr

**Sent:** Wednesday, May 20, 2020 6:23 PM

**To:** Adam, Stacey (FNIH) [T] < (b) (6) Judy Currier < (b) (6) Eric Hughes  
< (b) (6) LaVange, Lisa M < (b) (6) Sandeep Menon  
< (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah  
(NIH/NIAID) [E] < (b) (6) Price, Dionne (FDA/CDER) (b) (6) >; Rubin, Daniel B.  
(FDA/CDER) < (b) (6) Farley, John (FDA/CDER) < (b) (6) Karen Lynn Price  
(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) Wohl, David A (b) (6) Fischer, William A. II  
(b) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) Roa, Jhoanna (b) (6)  
; (b) (6) Kim, Peter (NIH/NIAID) [E] < (b) (6) Jonathan Li < (b) (6)  
Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) Kozak, Marina (OS/ASPR/BARDA)  
< (b) (6)  
**Cc:** DeMarcus, Forrest (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan  
< (b) (6) Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)  
Jhoanna Roa < (b) (6) Smith, David < (b) (6) Paul Klekotka  
(b) (6) Ajay Nirula (b) (6) Elsaid, Olivia < (b) (6) Robert Jan  
Benschop (b) (6) Lei Shen (b) (6)  
**Subject:** RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Here is my question for the group – especially Michael, John and Lisa

My question is whether there could be an interim “activity” analysis similar to the futility analysis listed below – the reason I ask is we have very little longitudinal data on the quantitative viral shedding and it is possible that this endpoint would have substantial power such that 50 patients per arm could provide an antiviral answer.

- If the Phase 2 portion of the Clinical mAb protocol is used for dose finding, this may be challenging with respect to size of the trial (number of treatment arms needed and available sample size per treatment arm). In addition, it may be appropriate to establish an interim futility analysis based on change in quantitative viral shedding to allow for discontinuation of a dose after e.g. 50 rather than 110 patients, or to allow early discontinuation of high doses due to safety findings.

Joe Eron MD

APAR0000005318-2517146

Professor of Medicine  
University of North Carolina at Chapel Hill  
School of Medicine  
(b) (6)

**From:** Adam, Stacey (FNIH) [T] < (b) (6) >

**Sent:** Wednesday, May 20, 2020 5:42 PM

**To:** Judy Currier < (b) (6) > Eric Hughes < (b) (6) > LaVange, Lisa M  
(b) (6) Sandeep Menon < (b) (6) > Proschan, Michael (NIH/NIAID) [E]  
< (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Price, Dionne (FDA/CDER)  
< (b) (6) > Rubin, Daniel B. (FDA/CDER) < (b) (6) > Farley, John (FDA/CDER)  
< (b) (6) > Karen Lynn Price < (b) (6) > (b) (6)  
(b) (6) (b) (6) (b) (6) Wohl, David A  
(b) (6) Fischer, William A. II < (b) (6) > Eron, Joseph J Jr  
(b) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) > Roa, Jhoanna (b) (6)  
(b) (6) Kim, Peter (NIH/NIAID) [E] < (b) (6) > Jonathan Li < (b) (6) >  
Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) > Kozak, Marina (OS/ASPR/BARDA)  
< (b) (6) >  
**Cc:** DeMarcus, Forrest < (b) (6) > Tountas, Karen (FNIH) [T] < (b) (6) > Wachtel, Jonathan  
< (b) (6) > Elizabeth Kim < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >  
Jhoanna Roa < (b) (6) > Eron, Joseph J Jr < (b) (6) > Smith, David  
< (b) (6) > Paul Klekotka < (b) (6) > Ajay Nirula < (b) (6) > Elsaid,  
Olivia < (b) (6) > Robert Jan Benschop < (b) (6) > Lei Shen < (b) (6) >  
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Dear mAb Outpatient WT,

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Also, attaching again the updated synopsis that was discussed with the mAb Steering Committee earlier today.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
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**From:** Eron, Joseph J Jr [ (b) (6) ]  
**Sent:** 5/20/2020 10:23:26 PM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [ (b) (6) ]; LaVange, Lisa M [ (b) (6) ]; Sandeep Menon [ (b) (6) ]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [ (b) (6) ]; d [ (b) (6) ]; (b) (6) ; (b) (6) [ (b) (6) ]; Wohl, David A [ (b) (6) ]; u; Fischer, William A. II [ (b) (6) ]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li [ (b) (6) ]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]  
**CC:** DeMarcus, Forrest [ (b) (6) ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) ]; Elizabeth Kim [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [ (b) (6) ]; Smith, David [ (b) (6) ]; Paul Klekotka [ (b) (6) ]; Ajay Nirula [ (b) (6) ]; Elsaid, Olivia [ (b) (6) ]; Robert Jan Benschop [ (b) (6) ]; Lei Shen [ (b) (6) ]  
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Joe Eron MD  
 Professor of Medicine  
 University of North Carolina at Chapel Hill

APAR0000005346-2517148

School of Medicine  
(b) (6)

**From:** Adam, Stacey (FNIH) [T] < (b) (6) >

**Sent:** Wednesday, May 20, 2020 5:42 PM

**To:** Judy Currier < (b) (6) > Eric Hughes < (b) (6) > LaVange, Lisa M  
< (b) (6) > Sandeep Menon < (b) (6) > Proschan, Michael (NIH/NIAID) [E]  
< (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Price, Dionne (FDA/CDER)  
< (b) (6) > Rubin, Daniel B. (FDA/CDER) < (b) (6) > Farley, John (FDA/CDER)  
< (b) (6) > Karen Lynn Price < (b) (6) > (b) (6)  
< (b) (6) > (b) (6) < (b) (6) > Wohl, David A  
< (b) (6) > Fischer, William A. II < (b) (6) > Eron, Joseph J Jr  
< (b) (6) > Javan, Arzhang (NIH/NIAID) [E] < (b) (6) > Roa, Jhoanna (b) (6)  
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Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) > Kozak, Marina (OS/ASPR/BARDA)  
< (b) (6) >  
**Cc:** DeMarcus, Forrest < (b) (6) > Tountas, Karen (FNIH) [T] < (b) (6) > Wachtel, Jonathan  
< (b) (6) > Elizabeth Kim < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >  
Jhoanna Roa < (b) (6) > Eron, Joseph J Jr < (b) (6) > Smith, David  
< (b) (6) > Paul Klekotka < (b) (6) > Ajay Nirula < (b) (6) > Elsaid,  
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**Stacey J. Adam, PhD**

Director, Cancer

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**From:** Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]  
**Sent:** 4/15/2020 9:27:47 PM  
**To:** Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];  
(b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) (b) (6)  
Arvin, Ann [ (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) Haynes, Barton [ (b) (6)  
(b) (6) (b) (6) Marks, Peter (FDA/CBER) [ (b) (6) Mascola, John  
(NIH/VRC) [E] (b) (6) ], Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) Offit, Paul  
[ (b) (6) (b) (6) Seals, Jonathan (OS/ASPR/BARDA) (b) (6)  
(b) (6) Tal Zaks [ (b) (6) (b) (6)  
**CC:** Tolman, Brett [ (b) (6) (b) (6) Kozlowski, Mary (NIH/NCI) [C]  
[ (b) (6) Johnson, Maureen (NIH/NCI) [E] (b) (6) (b) (6)  
(b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]  
[ (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [ (b) (6)  
Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wood, Gretchen (NIH/OD) [E]  
[ (b) (6) Wholley, David (FNIH) [T] [ (b) (6) Menetski, Joseph (FNIH) [T]  
(b) (6) Adam, Stacey (FNIH) [T] [ (b) (6) Tountas, Karen (FNIH) [T] (b) (6)  
James, Stephanie (FNIH) [T] [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [ (b) (6)  
Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Kurilla, Michael  
(NIH/NCATS) [E] [ (b) (6) Read, Sarah (NIH/NIAID) [E] [ (b) (6) Young, John  
(b) (6) Gonzalez, Nina [ (b) (6) (b) (6)  
(b) (6) Wachtel, Jonathan (b) (6) Arvin, Ann  
[ (b) (6) Anderson, Margaret [ (b) (6) Marston, Hilary (NIH/NIAID) [E]  
(b) (6) ]; Bethany Stokes (b) (6) ]

**Subject:** ACTIV Vaccines Working Group meeting  
**Location:** Webex: <https://nih.webex.com/n> (b) (6)  
**Start:** 4/20/2020 1:00:00 PM  
**End:** 4/20/2020 2:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann;  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) Haynes, Barton; (b) (6)  
(b) (6) Marks, Peter (FDA/CBER), Mascola, John (NIH/VRC) [E]; Messonnier, Nancy  
(CDC/DDID/NCIRD/OD), Offit, Paul; (b) (6) Seals, Jonathan (OS/ASPR/BARDA);  
(b) (6) Tal Zaks  
**Optional Attendees:** Tolman, Brett, (b) (6) Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E];  
(b) (6) (b) (6) (b) (6) (b) (6)  
Austin, Sarah (NIH/NIAID) [E], (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis  
(NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T], Menetski, Joseph (FNIH) [T]; Adam, Stacey  
(FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers,  
Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Gonzalez, Nina;  
(b) (6) (b) (6) Wachtel, Jonathan; Ann Arvin; Anderson,  
Margaret; Marston, Hilary (NIH/NIAID) [E]; Bethany Stokes

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CC:



[/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Melencio, Cheryl (FNIH)  
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Tolman, Brett  
 [ (b) (6) Alvarez, Rosa [ (b) (6) Gonzalez, Nina [ (b) (6)  
 Stratton, Benjamin [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange  
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm];  
 Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B.  
 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary  
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q.  
 [ (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [ (b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Colvis,  
 Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E]  
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 [ (b) (6) Biggs, Mary [ (b) (6) Butcher, Tina [ (b) (6)  
 Demarcus [ (b) (6) Macone, Erin [ (b) (6) Melencio, Cheryl (FNIH) [T]  
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan  
 [ (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [ (b) (6) Rose Li Central Account [ (b) (6) Lucas Smalldon  
 [ (b) (6) ; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; [ (b) (6) Mollica, Linda /US  
 [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [ (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [ (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [ (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Bethany Stokes [ (b) (6) Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]

**Attachments:** ACTIV\_TX-Clinical WG Meeting\_20201210.pdf

**Location:** <https://fnih.zoom.us/j> (b) (6)

**Start:** 12/10/2020 6:00:00 PM

**End:** 12/10/2020 7:00:00 PM

**Show Time As:** Tentative

**Recurrence:** (none)

every Thursday from 1:00 PM to 2:00 PM

**Required Attendees:** Jacqueline Kirchner; Garner, Carl; Sizemore, Christine (NIH/FIC) [E]; Bozette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] [ (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Coady, Sean (NIH/NHLBI) [E]; Petrovick, Martha - 0449 - MITLI; (b) (6)

**Optional Attendees:** Anderson, Margaret; Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; Stratton, Benjamin; jennifer.j. (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa, Alex David; Lumsden, Joanne (NIH/NCATS) [C]

Dear ACTIV TX-Clinical WG,



Please find attached the slides for today's meeting. Looking forward to see you all there.

Thanks,  
Stacey

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